IN RE: Bard IVC Filters Products Liability Litigation
USDC, District of Arizona, Case No. 2:15-MD-02641-DGC

DEFENDANTS' REPLY IN SUPPORT OF ITS MOTION AND INCORPORATED MEMORANDUM FOR PROTECTIVE ORDER REGARDING REPORT OF DR. JOHN LEMANN

LIST OF EXHIBITS

Exhibit A	D. Ciavarella Deposition Transcript, Nov. 12, 2013	
Exhibit B	MAUDE database disclaimer	
Exhibit C	HHE, Apr. 27, 2004	FILED UNDER SEAL
Exhibit D	*Peterson* Order, Mar. 3, 2015	
Exhibit E	2001 SIR Guidelines	
Exhibit F	Letter to FDA, Oct. 5, 2004	
Exhibit G	FDA Draft Guidance	
Exhibit H	*Phillips* Docket Entry re Michael Freeman	

EXHIBIT A

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN DIEGO, EAST COUNTY REGIONAL CENTER

- - -

MARY GIORDANO, individually and on Behalf of the Estate of Jacqueline Keith and other qualified survivors, Plaintiffs,	
vs.	Case No. 37-2011-00069363-CU-PO-EC
C.R. BARD, INC., a corporation, BARD PERIPHERAL VASCULAR INC., a corporation, THOMAS BRANNIGAN, M.D., an individual, FRANKLIN KALMAR, M.D., an individual, JULIE LAIDIG, M.D., an individual, SHARP GROSSMONT HOSPITAL, a corporation, SHARP HEALTHCARE, a corporation, and DOES 1 through 100 inclusive, Defendants.	

- - -

Tuesday, November 12, 2013

- - -

Videotaped Deposition of DAVID CIAVARELLA, M.D., held at Short Hills Hilton, 41 John F. Kennedy Parkway, Short Hills, New Jersey, on the above date, beginning at 9:43 a.m., before Kimberly A. Overwise, a Certified Realtime Reporter and Notary Public.

- - -

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.591.5672 fax
deps@golkow.com

APPEARANCES:

LOPEZ McHUGH LLP
BY: RAMON ROSSI LOPEZ, ESQ.
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660
949-737-1501
rlopez@lopezmchugh.com
Counsel for Plaintiffs

HEAVISIDE REED ZAIC
BY: JULIA REED ZAIC, ESQ.
312 Broadway Street, Suite 203
Laguna Beach, CA 92651
949-715-5120
julia@hrzlaw.com
Counsel for Plaintiffs

BABBITT, JOHNSON, OSBORNE & LeCLAINCHE, P.A.
BY: JOSEPH R. JOHNSON, ESQ.
1641 Worthington Road, Suite 100
West Palm Beach, FL 33401
561-684-2500
jjohnson@babbitt-johnson.com
Counsel for Plaintiffs

NELSON MULLINS RILEY & SCARBOROUGH LLP
BY: TAYLOR TAPLEY DALY, ESQ.
Atlantic Station
201 17th Street NW, Suite 1700
Atlanta, GA 30363
404-322-6158
taylor.daly@nelsonmullins.com
Counsel for Defendant C.R. Bard, Inc.

ALSO PRESENT:
Catherine Smalfus, videographer

APPEARANCES VIA TELEPHONE:

HEAVISIDE REED ZAIC
BY: LAURA SMITH, ESQ.
312 Broadway Street, Suite 203
Laguna Beach, CA 92651
949-715-5120
Counsel for Plaintiffs

KARON & DALIMONTE, LLP
BY: JOHN A. DALIMONTE, ESQ.
85 Devonshire Street, Suite 1000
Boston, MA 02109
617-367-3311
johndalimonte@kdlaw.net
Counsel for Plaintiffs

CLARK, FOUNTAIN, LA VISTA, PRATHER, KEEN & LITTKY-RUBIN, LLP
BY: CYRUS S. NIAKAN, ESQ.
1919 N. Flagler Drive
West Palm Beach, FL 33407
561-899-2111
cniakan@clarkfountain.com
Counsel for Plaintiff Anthony Payne

NEIL, DYMOTT, FRANK, McFALL & TREXLER, APLC
BY: ALAN B. GRAVES, ESQ.
1010 Second Avenue, Suite 2500
San Diego, CA 92101
619-238-2286
agraves@neildymott.com
Counsel for Defendant Julie Laidig, M.D.

LAFOLLETTE, JOHNSON, DEHAAS, FESLER & AMES
BY: N. BEN CRAMER, ESQ.
501 W. Broadway, Suite 800
San Diego, CA 92101
619-400-4978
bcramer@ljdfa.com
Counsel for Defendant Franklin Kalmar, M.D.

of your own files somewhere, whether they be electronic or hard copy or archived files, that in any way relate to Bard IVC filters?

A The only -- I mean, I had files at one time. They were all given over to our attorneys. And same thing with my electronic documents.

Q Okay. Whether they be company files or your own personal files, those were all given over to lawyers?

A Everything I had related to it.

Q All right. You've been with Bard since, I think, May of 2004?

A Yes.

Q Still there?

A Yes.

Q In what capacity?

A I have the same title as a staff vice president, corporate clinical affairs.

Q Okay. Are you with -- are you technically employed by C.R. Bard or are you employed by a division of C.R. Bard?

A C.R. Bard.

Q Before the deposition started I was given a CV. And I'll give you -- and I've

vice president of regulatory affairs. I interviewed with his boss, Chris Ganser, who was vice president of regulatory sciences. I interviewed with Tim Ring, then and now the CEO.

Q All right.

A And I had a telephone interview with Dr. Lehmann.

Q How about Mr. Weiland?

A I don't remember being interviewed by Mr. Weiland.

Q What was his position at the time?

A Chief operating officer.

Q Was Brian Barry a doctor?

A No.

Q How about Chris Ganser?

A No.

Q How about Tim Ring?

A No.

Q How about Mr. Weiland?

A No.

Q And then when you were being interviewed for this job as the medical affairs -- is it director? How did you call -- what did you call yourself?

A Well, my title is -- current title is

staff vice president, corporate clinical affairs.

Q Okay. But in early -- in the 2004, '5, '6, '7.

A I think I said medical affairs or medical director at various times. What I was trying to communicate there is that -- is that the current title of medical affairs medical director were responsibilities that I assumed at that time, as I was the only physician.

Q Okay. So if I say medical affairs director or medical director, I mean, it's basically what your job was?

A Yes.

Q When you were interviewing for this position, did anyone advise you that they were involved in a crisis as it pertained to the Recovery filter and you'd be stepping into that once you came on board?

A Well, yes; except I would not say that it was put forth as a crisis. When I interviewed with Mr. Ring, Tim Ring, he mentioned that this was an ongoing issue and made me aware of it.

Q And they needed help?

EXHIBIT B

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Manufacturer and User Facility Device Experience Database - (MAUDE)

MAUDE data represents reports of adverse events involving medical devices. The download data files consist of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. The searchable database data contains the last 10 year's data. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under **21 CFR 803.19 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=803.19)**.

An **on-line search (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM)** is available which allows you to search the CDRH's database information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE data is current through the end of the previous month. FDA seeks to include all reports received prior to the update. However, the inclusion of some reports may be delayed by technical or clerical difficulties.

MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.

Please be aware that reports regarding device trade names may have been submitted under different manufacturer names. Searches only retrieve records that contain the search term(s) provided by the requester.

The data is also available in zipped files for downloading. The data is updated on a weekly basis.

These files were then compressed ("zipped") in order to save space. For these files to be useful to you, you'll first have to download them, unzip them, and then import them into a database or word processor for your further processing.

DISCLAIMER: Section 21 CFR 803.16 states that "A report or other information submitted by a reporting entity under this part, and any release by FDA of that report or information, does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event. The reporting entity need not admit and may deny that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof,

caused or contributed to a reportable event." In addition, some firms have submitted their own additional disclaimer statements. A file of those disclaimers will be placed on the web shortly.

The releasable MAUDE data is presented in four logical records types. For this data to be meaningful, you should download all four types of files. The four record formats contain all releasable information on **MEDWATCH Form 3500 (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf)**.

Downloading Hint: When downloading the MAUDE data files to a database such as Microsoft Access, it is recommended that you first open, then save the data file in Microsoft WORD. This will add an "end of record" marker to each MAUDE record that can be recognized by Microsoft ACCESS. For files such as the FOIDEV files, you may need to put in an extra character at the end of the first record prior to importing the file, otherwise the last column of data may be lost.

Master Event Data: A distinct master event data record will be present for each source reporting anevent. In other words, if a User Facility, Distributor, Manufacturer, and voluntary submitter all report an event, there will be four event records. These individual source records are related via the EVENT KEY. EVENT KEY is an internally-generated key which links multiple sources to a single event.

Device Data: Record Type 2 contains information related to the device(s) involved in the event.

Patient Data: Record Type 3 contains information related to the patient(s) involved in the event.

Text Data: Record Type 4 contains textual information from MEDWATCH Form Sections B5, H3, and H10.

All record types are linked via the MDR REPORT KEY.

For distributor reports which have had subsequent manufacturer reports, a special data element, MANUFACTURER LINK FLAG, will be set to 'Y'. In this case, the DISTRIBUTOR information (Section F on the master event data record) will be present; otherwise, these data elements will be blank.

The following files are available: (File Sizes are approximate)

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
mdrfoi.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/mdrfoi.zip)	24604KB	238056KB	744458	MAUDE Base records received to date for 2015

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
mdrfoiadd.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/mdrfoiadd.zip)	2285KB	23321KB	71220	New MAUDE Base records for the current month.
mdrfoichange.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/mdrfoichange.zip)	4983KB	47296KB	144224	MAUDE Base data updates: changes to existing Base data.
mdrfoithru2014.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/mdrfoithru2014.zip)	142765KB	1232037KB	4083820	Master Record through 2014
patient.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/patient.zip)	2641KB	21044KB	744536	MAUDE Patient records received to date for 2015
patientadd.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/patientadd.zip)	155KB	1877KB	71223	New MAUDE Patient records for the current month.
patientchange.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/patientchange.zip)	477KB	4126KB	144223	MAUDE Patient data updates: changes to existing Base data.
patientthru2014.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/patientthru2014.zip)	21835KB	143581KB	4086626	Patient Record through 2014
deviceproblemcodes.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/deviceproblemcodes.zip)	9KB	27KB	988	Device Data for problemcodes

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
foidev.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev.zip)	23108KB	138622KB	745913	Device Data for foidev
foidev1998.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev1998.zip)	3205KB	17539KB	63440	Device Data for foidev1998
foidev1999.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev1999.zip)	2764KB	14798KB	52880	Device Data for foidev1999
foidev2000.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2000.zip)	2815KB	15159KB	53293	Device Data for foidev2000
foidev2001.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2001.zip)	3040KB	16283KB	58067	Device Data for foidev2001
foidev2002.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2002.zip)	3219KB	17264KB	65808	Device Data for foidev2002
foidev2003.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2003.zip)	3372KB	17953KB	67844	Device Data for foidev2003
foidev2004.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2004.zip)	2897KB	14884KB	57045	Device Data for foidev2004
foidev2005.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2005.zip)	4427KB	24661KB	93413	Device Data for foidev2005

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
foidev2006.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2006.zip)	6109KB	34443KB	134516	Device Data for foidev2006
foidev2007.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2007.zip)	5602KB	31935KB	149334	Device Data for foidev2007
foidev2008.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2008.zip)	5207KB	32883KB	164611	Device Data for foidev2008
foidev2009.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2009.zip)	8046KB	39164KB	221478	Device Data for foidev2009
foidev2010.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2010.zip)	12043KB	60223KB	338824	Device Data for foidev2010
foidev2011.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2011.zip)	14257KB	73806KB	415738	Device Data for foidev2011
foidev2012.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2012.zip)	17989KB	91648KB	521770	Device Data for foidev2012
foidev2013.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2013.zip)	22026KB	114009KB	639192	Device Data for foidev2013
foidev2014.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2014.zip)	27608KB	157206KB	869370	Device Data for foidev2014

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
foidevadd.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidevadd.zip)	2416KB	13484KB	71327	New MAUDE Device data for the current month.
foidevchange.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidevchange.zip)	4913KB	27650KB	144505	Device data updates: changes to existing Device data and additional Device data for existing Base records.
foidevproblem.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidevproblem.zip)	6899KB	23013KB	1710080	Device Data for foidevproblem
foidevthru1997.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidevthru1997.zip)	6001KB	31217KB	136917	Device Data through foidevthru1997
foitext.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext.zip)	149512KB	628276KB	1597994	Narrative Data received to date for 2015
foitext1996.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext1996.zip)	3471KB	13854KB	45320	Narrative Data for 1996
foitext1997.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext1997.zip)	10020KB	43208KB	140703	Narrative Data for 1997
foitext1998.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext1998.zip)	8257KB	35948KB	105288	Narrative Data for 1998

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
foitext1999.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext1999.zip)	7205KB	30804KB	84968	Narrative Data for 1999
foitext2000.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2000.zip)	9055KB	38741KB	107575	Narrative Data for 2000
foitext2001.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2001.zip)	9641KB	39950KB	114526	Narrative Data for 2001
foitext2002.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2002.zip)	10416KB	43824KB	120528	Narrative Data for 2002
foitext2003.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2003.zip)	9996KB	43169KB	118854	Narrative Data for 2003
foitext2004.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2004.zip)	9728KB	40855KB	96689	Narrative Data for 2004
foitext2005.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2005.zip)	15096KB	65231KB	177109	Narrative Data for 2005
foitext2006.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2006.zip)	20554KB	90986KB	234272	Narrative Data for 2006
foitext2007.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2007.zip)	20178KB	91196KB	237466	Narrative Data for 2007

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
foitext2008.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2008.zip)	20916KB	101156KB	264918	Narrative Data for 2008
foitext2009.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2009.zip)	40714KB	147617KB	387876	Narrative Data for 2009
foitext2010.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2010.zip)	69781KB	261319KB	696944	Narrative Data for 2010
foitext2011.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2011.zip)	99825KB	383992KB	968235	Narrative Data for 2011
foitext2012.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2012.zip)	135606KB	508802KB	1234828	Narrative Data for 2012
foitext2013.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2013.zip)	147270KB	569421KB	1480794	Narrative Data for 2013
foitext2014.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2014.zip)	182304KB	711731KB	1880468	Narrative Data for 2014
foitextadd.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitextadd.zip)	12318KB	54123KB	131403	New MAUDE Narrative data for the current month.

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
foitextchange.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitextchange.zip)	28255KB	140088KB	323713	Narrative data updates: changes to existing narrative data and additional narrative data for existing base records.
foitextthru1995.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitextthru1995.zip)	3331KB	16780KB	27404	Narrative data through 1995

[**Accessibility (http://www.hhs.gov/siteinfo/508web.html)**]

Note: This documentation is intended to be used in conjunction with a copy of Medwatch Form **3500A (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048334.pdf)** and **3500 (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf)**.

Record/Data Characteristics:

- The data has one record per line, with the data fields in a pipe-delimited, (i.e., "|") format
- All data elements are alpha-numeric
- All text fields contain whatever data was provided/entered. If no information was provided/entered the field will be left empty. If an asterisk ("*") is present, it represents what was entered on the 3500/3500A.
- All "FLAG" data elements have the value of "Y" for Yes, "N" for No, or are blank if no data was available/entered.
- All fields identified as multiply-occurring represent data elements which may have multiple values. Each value will be present in the field, separated by a comma. The word "OTHER" may appear as one of the values if the "Other" box was checked off. If the whole field is blank, no data was reported/entered.
- Section G CONTACT address information may not necessarily be the address where the device is manufactured.

Special Note for REPORT NUMBER data element:

The REPORT NUMBER data element represents Manufacturer Report Number, Distributor Report Number, or internally-generated voluntary report number, depending on the source of the record.

This REPORT NUMBER field will be blank when:

- User Facility submitted the report
- Distributor report has not been followed by a subsequent Manufacturer report.

Special Notes for Voluntary Reports and User Facility Malfunction Reports:

The only data elements which will be present on the Master Event Record will be:

- NEW RECORD
- DEVICE EVENT KEY
- REPORT SOURCE CODE
- MDR REPORT KEY
- EVENT KEY
- Section B

All other data elements will be blank.

MDRFOI file contains following 75 fields, delimited by pipe (|), one record per line:

1. MDR Report Key
2. Event Key
3. Report Number
4. Report Source Code

    P = Voluntary report
    U = User Facility report
    D = Distributor report
    M = Manufacturer report

5. Manufacturer Link Flag (internal information flag)
6. Number Devices in Event (if source code is 'P', field will be null)
7. Number Patient in Event (if source code is 'P', field will be null)
8. Date Received

SECTION-B

9. Adverse Event Flag (B1)
10. Product Problem Flag (B1)
11. Date Report (B4)
12 Date of Event (B3) -- new added, 2006
13 Single Use Flag (Reprocessor Flag) (D8) -- new added, 2006
14 Reporter Occupation Code (E3) -- new added, 2006

---

* INVALID DATA	300 OTHER CAREGIVERS
000 OTHER	301 DENTAL ASSISTANT
001 PHYSICIAN	302 HOME HEALTH AIDE
002 NURSE	303 MEDICAL ASSISTANT

0HP HEALTH PROFESSIONAL
0LP LAY USER/PATIENT
100 OTHER HEALTH CARE PROFESSIONAL
101 AUDIOLOGIST
102 DENTAL HYGIENIST
103 DIETICIAN
104 EMERGENCY MEDICAL TECHNICIAN
105 MEDICAL TECHNOLOGIST
106 NUCLEAR MEDICINE TECHNOLOGIST
107 OCCUPATIONAL THERAPIST
108 PARAMEDIC
109 PHARMACIST
110 PHLEBOTOMIST
111 PHYSICAL THERAPIST
112 PHYSICIAN ASSISTANT
113 RADIOLOGIC TECHNOLOGIST
114 RESPIRATORY THERAPIST
115 SPEECH THERAPIST
116 DENTIST
304 NURSING ASSISTANT
305 PATIENT
306 PATIENT FAMILY MEMBER OR FRIEND
307 PERSONAL CARE ASSISTANT
400 SERVICE AND TESTING PERSONNEL
401 BIOMEDICAL ENGINEER
402 HOSPITAL SERVICE TECHNICIAN
403 MEDICAL EQUIPMENT COMPANY TECHNICIAN/REPRESENTATIVE
404 PHYSICIST
405 SERVICE PERSONNEL
499 DEVICE UNATTENDED
500 RISK MANAGER
600 ATTORNEY
999 UNKNOWN
NA NOT APPLICABLE
NI NO INFORMATION
UNK UNKNOWN

SECTION-E (if source code is 'P', Section E to H will contain no data)

15. Health Professional (E2)
16. Initial Report to FDA (E4)

Y = Yes
N = No
U = Unknown
* = No answer provided

SECTION-F

17. Distributor Name (F3) -- if report source code = 'M' and Manufacturer link flag is 'Y', fields 14 - 20 will contain data; otherwise they will be null
18. Distributor Address line 1 (F3)
19. Distributor Address line 2 (F3)
20. Distributor City (F3)
21. Distributor State Code (F3)
22. Distributor Zip Code (F3)
23. Distributor Zip Code Ext (F3)
24. Date Facility Aware (F6)
25. Type of Report (F7) !multiple submission type, separate by ','

I = Initial submission
F = Followup
X = Extra copy received
O = Other information submitted

26. Report Date (F8)
27. Report to FDA (F11)
28. Date Report to FDA (F11)
29. **Event Location** (F12)
30. Report to Manufacturer (F13)
31. Date Report to Manufacturer (F13)
32. Manufacturer Name (F14)
33. Manufacturer Address line 1 (F14)
34. Manufacturer Address line 2 (F14)
35. Manufacturer City (F14)
36. Manufacturer State Code (F14)
37. Manufacturer Zip Code (F14)
38. Manufacturer Zip Code Ext (F14)
39. Manufacturer Country Code (F14)
40. Manufacturer Postal Code (F14)

SECTION-G (only for report source 'M', others sources will be null)

41. Manufacturer Contact Title Name (G1)
42. Manufacturer Contact First Name (G1)
43. Manufacturer Contact Last Name (G1)
44. Manufacturer Contact Street 1 (G1)
45. Manufacturer Contact Street 2 (G1)
46. Manufacturer Contact City (G1)
47. Manufacturer Contact State Code (G1)
48. Manufacturer Contact Zip Code (G1)
49. Manufacturer Contact Zip Code Ext (G1)
50. Manufacturer Contact Country Code
51. Manufacturer Contact Postal Code
52. Manufacturer Contact Phone No Area Code (G1)
53. Manufacturer Contact Phone No Exchange (G2)
54. Manufacturer Contact Phone No (G2)
55. Manufacturer Contact Phone No Ext (G2)
56. Manufacturer Contact Phone No Country Code
57. Manufacturer Contact Phone No City Code
58. Manufacturer Contact Phone No Local
59. Manufacturer G1 Name (G1)
60. Manufacturer G1 Street 1 (G1)
61. Manufacturer G1 Street 2 (G1)
62. Manufacturer G1 City (G1)
63. Manufacturer G1 State Code (G1)
64. Manufacturer G1 Zip Code (G1)
65. Manufacturer G1 Zip Code Ext (G1)
66. Manufacturer G1 Country Code
67. Manufacturer G1 Postal Code
68. Source Type (G3) -- multiple source type, separate by ','

    00 Other
    01 Foreign
    02 Study

03 Literature
04 Consumer
05 Health Professional
06 User facility
07 Company representation
08 Distributor
99 Unknown
* Invalid data

69. Date Manufacturer Received (G4)

SECTION-H
70. Device Date Of Manufacture (H4)
71. Single Use Flag (H5)
72. Remedial Action (H7) -- multiple source type, separate by ','

RC = Recall
RP = Repair
RL = Replace
RB = Relabeling
OT = Other
NO = Notification
IN = Inspection
PM = Patient Monitoring
MA = Modification/Adjustment
* = Invalid Data

73. Previous Use Code (H8)
74. Removal/Correction Number (H9)
75. Event type (H1) -- only relevant for report sourcetype 'M'

D = Death
IN = Injury
IL = Injury
IJ = Injury
M = Malfunction
O = Other
* = No answer provided

DEVICE file contains following 45 fields, delimited by pipe (|), one record per line:

1. MDR Report Key
2. Device Event key
3. Implant Flag -- D6, new added; 2006
4. Date Removed Flag -- D7, new added; 2006; if flag in M or Y, print Date

U = Unknown
A = Not available
I = No information at this time
M = Month and year provided only, day defaults to 01
Y = Year provided only, day defaulted to 01, month defaulted to January

5. Device Sequence No -- from device report table
6. Date Received (from mdr_document table)

SECTION-D

7. Brand Name (D1)
8. Generic Name (D2)
9. Manufacturer Name (D3)
10. Manufacturer Address 1 (D3)
11. Manufacturer Address 2 (D3)
12. Manufacturer City (D3)
13. Manufacturer State Code (D3)
14. Manufacturer Zip Code (D3)
15. Manufacturer Zip Code ext (D3)
16. Manufacturer Country Code (D3)
17. Manufacturer Postal Code (D3)
18. Expiration Date of Device (D4)
19. Model Number (D4)
20. Catalog Number (D4)
21. Lot Number (D4)
22. Other ID Number (D4)
23. **Device Operator** (D5)
24. Device Availability (D10)

    Y = Yes
    N = No
    R = Device was returned to manufacturer
    * = No answer provided

25. Date Returned to Manufacturer (D10)
26. Device Report Product Code
27. Device Age (F9)
28. Device Evaluated by Manufacturer (H3)

    Y = Yes
    N = No
    R = Device not returned to manufacturer
    * = No answer provided

BASELINE SECTION (for records prior to 2009)

29. Baseline brand name
30. Baseline generic name
31. Baseline model no
32. Baseline catalog no
33. Baseline other id no
34. Baseline device family
35. Baseline shelf life contained in label

    Y = Yes
    N = No

A = Not applicable
* = No answer provided

36. Baseline shelf life in months
37. Baseline PMA flag
38. Baseline PMA no
39. Baseline 510(k) flag
40. Baseline 510(k) no
41. Baseline preamendment
42. Baseline transitional
43. Baseline 510(k exempt flag
44. Baseline date) first marketed
45. Baseline date ceased marketing

PATIENT file contains following 5 fields, delimited by pipe (|), one record per line:

1. MDR Report Key (from patient report table)
2. Patient Sequence Number (from patient report table)
3. Date Received (from mdr_document table)
4. Sequence Number||','|| Treatment -- multiple source type, separate by ';'
5. Sequence Number||','|| Outcome -- multiple source type, separate by ';'

L - Life Threatening
H - Hospitalization
S - Disability
C - Congenital Anomaly
R - Required Intervention
O - Other
* - Invalid Data
U - Unknown
I - No Information
A - Not Applicable
D - Death

TEXT file contains following 6 fields, delimited by pipe (|), one record per line:

1. MDR Report Key
2. MDR Text Key
3. Text Type Code (D=B5, E=H3, N=H10 from mdr_text table)
4. Patient Sequence Number (from mdr_text table)
5. Date Report (from mdr_text table)
6. Text (B5, or H3 or H10 from mdr_text table)

FOIDEVPROBLEM contains following 2 fields, delimited by pipe (|), one record per line:

1. MDR Report Key
2. Device Problem Code -- (F10) new added; 2006

DEVICEPROBLEMCODES contains following 2 fields, delimited by pipe (|), one record per line:

1. Device Problem Code
2. Problem Description

Device Operator Code Key

* INVALID DATA
0 OTHER
1 PHYSICIAN
2 NURSE
0HP HEALTH PROFESSIONAL
0LP LAY USER/PATIENT
100 OTHER HEALTH CARE PROFESSIONAL
101 AUDIOLOGIST
102 DENTAL HYGIENIST
103 DIETICIAN
104 EMERGENCY MEDICAL TECHNICIAN
105 MEDICAL TECHNOLOGIST
106 NUCLEAR MEDICINE TECHNOLOGIST
107 OCCUPATIONAL THERAPIST
108 PARAMEDIC
109 PHARMACIST
110 PHLEBOTOMIST
111 PHYSICAL THERAPIST
112 PHYSICIAN ASSISTANT
113 RADIOLOGIC TECHNOLOGIST
114 RESPIRATORY THERAPIST
115 SPEECH THERAPIST
116 DENTIST
300 OTHER CAREGIVERS
301 DENTAL ASSISTANT
302 HOME HEALTH AIDE
303 MEDICAL ASSISTANT
304 NURSING ASSISTANT
305 PATIENT
306 PATIENT FAMILY MEMBER OR FRIEND
307 PERSONAL CARE ASSISTANT
400 SERVICE AND TESTING PERSONNEL
401 BIOMEDICAL ENGINEER
402 HOSPITAL SERVICE TECHNICIAN
403 MEDICAL EQUIPMENT COMPANY TECHNICIAN/REPRESENTATIVE
404 PHYSICIST
405 SERVICE PERSONNEL
499 DEVICE UNATTENDED
500 RISK MANAGER
600 ATTORNEY
999 UNKNOWN
NA NOT APPLICABLE
NI NO INFORMATION
UNK UNKNOWN

Event Location Code Key

* INVALID DATA
000 OTHER
001 HOSPITAL
002 HOME
003 NURSING HOME
004 OUTPATIENT TREATMENT FACILITY
005 OUTPATIENT DIAGNOSTIC FACILITY
006 AMBULATORY SURGICAL FACILITY
500 HOSPITAL
501 CATHETERIZATION SUITE
609 IMAGING CENTER - MOBILE
610 IMAGING CENTER - STATIONARY
611 LABORATORY
612 MOBILE HEALTH UNIT
613 MRI CENTERS
614 PSYCHIATRIC CENTER - WALK IN, OTHER
615 TUBERCULOSIS CLINIC
616 URGENT CARE CENTER
617 OUTPATIENT DIAGNOSTIC FACILITY
700 LONG-TERM CARE FACILITY
701 HOSPICE

502 CRITICAL CARE UNIT
503 DIALYSIS UNIT
504 EMERGENCY ROOM
505 EXAMINATION ROOM
506 LABORATORY/PATHOLOGY DEPARTMENT
507 MATERNITY WARD - NURSERY
508 OPERATING ROOM
509 OUTPATIENT CLINIC/SURGERY
510 PATIENT'S ROOM OR WARD
511 RADIOLOGY DEPARTMENT
600 AMBULATORY HEALTH CARE FACILITY
601 AMBULATORY SURGICAL CENTER
602 BLOOD BANK
603 BLOODMOBILE
604 CATHETERIZATION LAB - FREE STANDING
605 CHEMOTHERAPY CENTER
606 CLINIC - WALK IN, OTHER
607 DIALYSIS CENTER
608 DRUG CLINIC
702 NURSING HOME
703 PSYCHIATRIC FACILITY
704 REHABILITATION CENTER
705 RETIREMENT HOME
810 PATIENT'S HOME
820 IN TRANSIT TO USER/MEDICAL FACILITY
830 PUBLIC VENUE
831 OUTDOORS
832 PARK
833 PLAYGROUND
834 PUBLIC BUILDING
835 SCHOOL
836 STREET
999 UNKNOWN
NA NOT APPLICABLE
NI NO INFORMATION
UNK UNKNOWN

More in Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)

Manufacturer and User Facility Device Experience Database - (MAUDE) (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm)

Medical Device Reporting Regulation History (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127985.htm)

eMDR – Electronic Medical Device Reporting (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/default.htm)

Event Problem Codes (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/EventProblemCodes/default.htm)

Manufacturer Evaluation Codes (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ManufacturerEvaluationCodes/default.htm)

EXHIBIT C

(Document Submitted Under Seal)

EXHIBIT D

UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

CAROL PETERSON, ET AL. **CIVIL ACTION**

VERSUS **NO.: 13-528-JJB-RLB**

C.R. BARD, INC., ET AL.

ORDER

Before the court is Defendants C. R. Bard, Inc.'s and Bard Peripheral Vascular, Inc.'s (collectively, "Bard" or "Defendants") Motion for Protective Order Regarding Discovery of Litigation Consultant's Report. (R. Doc. 33).[1] Defendants seek an order protecting a report prepared by Dr. John Lehmann in December 2004 ("the Lehmann Report") pursuant to the work product doctrine. Plaintiffs Carol Peterson and Richard Peterson (collectively, the "Petersons" or "Plaintiffs") oppose the motion. (R. Doc. 41). Defendants have filed a Reply. (R. Doc. 49).

Pursuant to this court's order (R. Doc. 56), Defendants submitted the Lehmann Report to the court for *in camera* inspection on February 18, 2015. Having reviewed the arguments of the parties, the Lehmann Report, and other documents submitted by the parties, and for the reasons stated below, Defendants' Motion for Protective Order is **GRANTED**.

I. Background

On August 13, 2013, the Petersons filed this diversity action against Bard alleging that a medical device—Bard's G2 Filter—placed in Carol Peterson's body on or about December 22, 2008, had "perforated, fractured and/or migrated on or about August 14, 2012." (R. Doc. 1 at 12). The Petersons allege that the device was not removed because removal would be life

[1] The court granted Bard's unopposed motion to file Exhibits B through Q, and Exhibits T through V, of its Motion for Protective Order, under seal. (R. Doc. 53). The exhibits are filed in the record under seal. (R. Docs. 54 through 54-18).

threatening. (R. Doc. 1 at 24). The Petersons allege causes of action for (1) negligence; (2) strict products liability – failure to warn; (3) strict products liability – design defects; (4) strict products liability – manufacturing defect; (5) breach of implied warranty of merchantability; (6) negligent misrepresentation; and (7) Loss of Consortium on Behalf of Plaintiff Richard Peterson. (R. Doc. 1 at 26-35). The Petersons seek recovery of punitive damages. (R. Doc. 35-36).

According to Bard, the G2 Filter is an "inferior vena cava ('IVC') filter, which is a venous interruption device designed to prevent pulmonary embolism by filtering blood to prevent blood clots from reaching and blocking the main artery of the lung or one of its branches." (R. Doc. 33-1 at 4). The G2 Filter is a second generation version of an earlier IVC filter marketed by Bard called the Recovery Filter. The Petersons note that in obtaining approval from the FDA to market the G2 Filter, Bard represented in a traditional 510(k) premarket notification that the G2 Filter is "identical" to the Recovery Filter System and that there were no "material changes or additional components" incorporated into the subsequent G2 Filter. (R. Doc. 41-1 at 3 (quoting R. Doc. 41-4 at 74)).

Bard represents that before marketing the G2 Filter in late 2005, and as early as "February 2004, Bard received threats of litigation from patients (or their lawyers) who allegedly experienced an adverse event with the Recovery Filter." (R. Doc. 33-1 at 4).[2] Bard also represents that "[b]etween April 2004 and September 2004, Bard received seven reports of alleged deaths potentially involving its Recovery Filters." (R. Doc. 33-1 at 4).[3] Finally, Bard represents that "throughout 2004, Bard was receiving reports that the Recovery Filter allegedly

[2] Bard submits various communications between it and patients raising potential claims against Bard regarding the Recovery Filter as Exhibits B through G to Bard's Motion to Compel. (R. Docs. 54 through 54-5).

[3] Bard submits entries from its complaint files evidencing these reports as Exhibits H through N to Bard's Motion. (R. Docs. 54-6 through 54-12).

fractured in numerous specific patients, migrated in numerous specific patients, and perforated the inferior vena cava in numerous patients." (R. Doc. 33-1 at 4).[4]

It is in this context that Bard contends that they contracted with Dr. John Lehmann, a former Bard employee, to conduct an independent study of their IVC filters and draft a report containing his findings. (R. Doc. 33-1 at 6). More specifically, Bard asserts that in November 2004 Dr. Lehmann "was contracted by the Bard Law Department to analyze the medical literature concerning IVC filters, analyze the complaints that Bard had received regarding the Recovery Filter, analyze the FDA's adverse event reporting database (MAUDE database)[5] to attempt to compare rates of adverse events seen with other manufacturers' IVC filters, and to prepare a written report with his findings." (R. Doc. 33-1 at 7). This contract is not before the court.[6]

On December 15, 2004, Dr. Lehmann submitted his report ("the Lehmann Report") to Donna Passero, Bard's assistant general counsel, who subsequently provided the report to Bard's general counsel and four "high level" employees outside the Law Department. (R. Doc. 33-1 at 7-8). The Lehmann Report was then provided to other five other "high level" employees (the "Product Assessment Team") who were directed to analyze the report and underlying data to

---

[4] Bard submits a compilation of various complaint files evidencing these reports as Exhibit O to Bard's Motion. (R. Doc. 54-13).

[5] "MAUDE" stands for "Manufacturer and User Facility Device Experience."

[6] Although Bard identified the contract as Exhibit R to their Motion, Bard did not file the contract under seal. (*See* R. Doc. 33-20). Instead, Bard requested the court to review the document through an *in camera* inspection. (R. Doc. 35). Plaintiffs opposed any *in camera* review by the court of any contract between Dr. Lehmann and Bard. (R. Doc. 42). The court deferred its decision regarding whether to review the contract until after it had the opportunity to review the Lehmann Report. (R. Doc. 56 at 4). Having reviewed the Lehmann Report, the arguments of the parties and other documents submitted in connection to the Motions, the court has determined that it does not need to review the contract through an *in camera* inspection to reach its conclusions in this order.

form a Remedial Action Plan ("RAP"). (R. Doc. 33-1 at 7-8; *see* R. Doc. 54-15 at 31).[7] Finally, the Lehmann Report was also provided to Bard's former Medical Director, Dr. David Ciaverella, M.D., to prepare a Health Hazard Evaluation ("HHE") "to identify a frequency category for serious injury for potential further action." (R. Doc. 33-1 at 8-9).[8]

Based on the foregoing timeline of events, Bard argues that the Lehmann Report is protected work product because the primary motivating purpose behind the document's creation was anticipated litigation. (R. Doc. 33-1 at 9-14). Bard highlights its counsel's involvement in the preparation of the document and that the document was created in response to numerous claims of adverse events, including deaths, regarding the Recovery Filter. (R. Doc. 33-1 at 9-14). Bard further contends that the Petersons has not proved both a substantial need for the Lehmann Report and an inability to obtain substantially equivalent material without undue hardship as required to overcome work product protection. (R. Doc. 33-1 at 15-17). Bard further argues that the Lehmann Report is not relevant because it concerned the Recovery Filter and not the G2 filter. (R. Doc. 33-1 at 15-16). Even if the Lehmann Report is relevant, Bard argues that the Petersons can obtain substantially equivalent material from the underlying sources used in the report. (R. Doc. 33-1 at 16-17). Finally, Bard also asserts that there was no waiver of work product protection on the basis that Bard substantially increased the likelihood that an adversary would come into possession of the Lehmann Report. (R. Doc. 33-1 at 17-18).

In response, the Petersons argue that the Lehmann Report is not protected work product. The Petersons argue that the Lehmann Report is a scientific evaluation of a product failure by an outside consultant in the ordinary course of business and distributed to multiple employees outside of Bard's legal department so that they could perform their non-litigation responsibilities.

[7] The RAP is attached to Bard's Motion as Exhibit T. (R. Doc. 54-16).

[8] The HHE is attached to Bard's Motion as Exhibit U. (R. Doc. 54-17).

Plaintiff asserts that federal regulations required Bard to prepare the RAP, which was entirely based on the Lehmann Report, and this is further evidence that the report was prepared in the ordinary course of business.

The Petersons raise two alternative arguments should the court conclude that the Lehmann Report is work product. First, the Petersons argue that they have a substantial need for the Lehmann Report and cannot, without undue hardship, obtain the substantial equivalent by any other means. In particular, the Petersons contends that the Lehmann Report proves that Bard had actual knowledge that the Recovery Filter was unreasonably dangerous in 2004, several years before Ms. Peterson was implanted with the next generation G2 Filter. (R. Doc. 41-1 at 2). The Petersons contend that without the Lehmann Report, they cannot discuss the analysis upon which Bard based their decisions to continue to sell the product, shortcut the FDA process, or fail to notify anyone of the problems with the filters.

Second, the Petersons argue that Bard has waived any work product protection by distributing the Lehmann Report to non-legal employees and third parties. Plaintiff claims that any work product protection was waived because certain Bard employees testified that they were given copies of the Lehmann Report in the ordinary course of business and were not told to keep it confidential or that it was prepared in anticipation of litigation. Plaintiff further contends that Dr. Ciavarella then further waived work product protection of the Lehmann Report by discussing its results at a Bariatric Surgeons Panel medical conference on February 12, 2005. (R. Doc. 41-1 at 18).

II. Law and Analysis

A. Whether the Lehmann Report is Work Product

The work product doctrine is a matter of federal procedural law in diversity cases. *See N. Am. Specialty Ins. Co. v. Iberville Coatings, Inc.*, No. 99-859, 2002 WL 34423316, at *3 (M.D. La. Mar. 22, 2002). The work-product doctrine is codified in Rule 26(b)(3) of the Federal Rules of Civil Procedure. "Ordinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent)." Fed. R. Civ. P. 26(b)(3)(A). The moving party may discover relevant information, however, if the "party shows that it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means." Fed. R. Civ. P. 26(b)(3)(A)(ii).

The party asserting protection under the work product doctrine has the burden of proving that the documents were prepared in anticipation of litigation. *Lasalle Bank N.A. v. Mobile Hotel Props., LLC*, No. 03-2225, 2004 WL 1238024, at *2 (E.D. La. June 3, 2004). In the Fifth Circuit, while litigation need not necessarily be imminent, the primary motivating purpose behind the creation of the document must be to aid in possible future litigation. *United States v. Davis*, 636 F.3d 1028, 1040 (5th Cir. 1981). The "[f]actors that courts rely on to determine the primary motivation for the creation of a document include the retention of counsel and his involvement in the generation of the document and whether it was a routine practice to prepare that type of document or whether the document was instead prepared in response to a particular circumstance." *Gator Marshbuggy Excavator L.L. C. v. M/V Rambler*, No. 03-3220, 2004 WL 1822843, at *3 (E.D. La. Aug. 12, 2004). Although the involvement of an attorney is not dispositive, it is a "highly relevant factor ... making materials more likely to have been prepared

in anticipation of litigation." *Carroll v. Praxair, Inc.*, No. 05-307, 2006 WL 1793656, at *2 (W.D. La. Jun. 28, 2006).

Bard asserts that the primary motivating purpose for creating the Lehmann Report was "anticipated litigation, as demonstrated by witness testimony and Bard documents." (R. Doc. 33-1 at 3). More specifically, Bard argues that the Lehmann Report is work product because (1) Bard hired Dr. Lehmann to create the Report after facing pending product liability claims and anticipated litigation; (2) Bard hired Dr. Lehmann to investigate medical and scientific issues and prepare a report for counsel's use in anticipated litigation; and (3) Dr. Lehmann wrote and submitted the report to Bard's Law Department. (R. Doc. 33-1 at 9-15). Bard represents in its motion that ten federal and state courts have ruled that the Lehmann Report is protected work product, but did not identify all of these decisions. (R. Doc. 33-1 at 2).[9]

In contrast, the Petersons claim that the Lehmann Report is not work product, but rather a report generated for business purposes. (R. Doc. 41-1 at 9-16). The Petersons argue that because the RAP was prepared for an ordinary business purpose, and the Lehmann Report was incorporated into and attached to the RAP, then the Lehmann Report must have also been created for a business purpose. Although the Petersons rely primarily on Louisiana case law

[9] Prior to the filing of the Peterson's Opposition, Bard filed a "Notice of Filing Supplemental Authority in Support of Their Motion for Protective Order" to alert the court that a decision from the Northern District of Texas on September 15, 2014 also found the Lehmann Report to qualify as work product. (R. Doc. 39). It now appears that there are seven federal district court decisions holding that the Lehmann Report is work product. *See Jones v. C.R. Bard, Inc.*, No. 13-cv-599 (N.D. Tex. Sept. 15, 2014) (R. Doc. 39-1); *Alexander v. C.R. Bard, Inc.*, No. 12-cv-5187 (N.D. Tex. Aug. 20, 2014) (R. Doc. 33-3); *Cason v. C.R. Bard. Inc.*, No. 12-cv-1288, ECF No. 87 (N.D. Ga. May 12, 2014); *Kilver v. CR. Bard, Inc.*, No. 13-cv-1219, ECF No. 69 (C.D. Ill. May 29, 2014); *Ebert* v. *CR. Bard, Inc.*, No. 12-cv-1253, 2014 WL 1632155 (E.D. Pa. Apr. 24, 2014); *Carr v. C.R. Bard, Inc.*, 297 F.R.D. 328 (N.D. Ohio 2014); *Phillips v. CR Bard, Inc.*, 290 F.R.D. 615 (D. Nev. 2013). In addition, there are four decisions from an Arizona Superior Court finding that the Lehmann Report is protected work product. *See Jones*, No. 13-cv-599, at * 11-12 (*citing Stesney v. CR. Bard, Inc.*, No. CV 2012-6103 (Ariz. Sup. Ct. Mar. 21, 2014); *Barkley v. CR. Bard, Inc.*, No. CV 2011-2150 (Ariz. Sup. Ct. Feb. 27, 2014); *Towlson v. C.R. Bard. Inc.*, No. CV 2011-22334 (Ariz. Sup. Ct. Feb. 27. 2014); *Rackliff. C.R. Bard. Inc.* No. CV 2011-21206 (Ariz. Sup. Ct. Feb. 12, 2014)).

interpreting Louisiana's work product rule, the Petersons acknowledge that the Fifth Circuit's "primary motivating purpose" test applies. (R. Doc. 41-1 at 10). The Petersons also rely on two decisions (one in federal court and one in state court) specifically holding that the Lehman Report is not protected work product.[10]

In support of their Motion for Protective Order, Defendants submitted an affidavit signed by Donna Passero, Bard's assistant general counsel, on February 12, 2013.[11] Ms. Passero states that she, in conjunction with Bard's Law Department, retained Dr. Lehmann "for the purpose of providing outside consultation services to the Law Department regarding anticipated and ongoing product liability litigation." (R. Doc. 54-14 at 2). Specifically, Ms. Passero states, "Dr. Lehmann was retained for the purpose of conducting an independent investigation and drafting a report concerning Bard's Recovery® Filter, which I -- in conjunction with Bard's Law Department -- requested for the purpose of providing Bard with legal advice concerning the Recovery® Filter and to prepare for and assist with anticipated and ongoing litigation." (R. Doc. 54-14 at 2-3). Ms. Passero further states that she informed Dr. Lehmann that "that his work was commissioned . . . to provide Bard with legal advice concerning the Recovery® Filter and to prepare for and assist with anticipated and ongoing litigation [and] that the results of his

[10] One federal magistrate judge has ruled (in a single order covering two cases) that the Lehmann Report is not work product. *See Tillman v. CR. Bard, Inc.*, No. 13-cv-222, ECF No. 80 (M.D. Fla. March 28, 2014); *Payne v. C.R. Bard, Inc.*, No. 11-cv-1582, ECF No. 144 (M.D. Fla. March 28, 2014). An appeal of this ruling is pending before the district judge in both cases. *See Tillman*, No. 13-cv-222, ECF No. 83; *Payne*, No. 11-cv-1582, ECF. No. 150. One California court has also held that it would not grant work product protection to the Lehmann Report. *See Jones*, No. 13-cv-599, at *11 (citing *Giordano v. C.R. Bard*, No. 37-2011-69363-CU-PO-EC (Cal. Sup. Ct. Apr. 10, 2013) (denying a clawback request for the report after it was inadvertently disclosed in a Minute Order with no explanation of the court's reasoning for its decision) (parenthetical by *Jones* court)).

[11] The Passero Affidavit is attached as Exhibit P to Bard's Motion. (R. Doc. 54-14). Although this document was filed under seal, it is referenced and quoted extensively in Bard's Motion, which was not filed under seal. (*See* R. Doc. 33-1 at 6-9, 17-18). The court's review confirms that the Passero Affidavit is consistent with the representations made in Bard's Motion. The substance of the Passero Affidavit is also discussed and quoted in previous decisions. *See, e.g.*, *Jones*, No. 13-cv-599, at *2-3; *Alexander*, No. 12-cv-5187, at *3.

investigation and his report should only be relayed to Bard's Law Department or to those whom Bard's Law Department may direct." (R. Doc. 54-14 at 3).

Ms. Passero states that during the course of his investigation, "Dr. Lehmann communicated with a small and limited number of Bard employees for the purpose of obtaining and providing information in order to fulfill his duties pursuant to the contract he signed with Bard's Law Department." (R. Doc. 54-14 at 3). Dr. Lehmann provided the report to Ms. Passero on or about December 15, 2004. (R. Doc. 54-14 at 3). Ms. Passero states that she then distributed the Lehmann Report "to five Bard employees (one of whom was a member of the Bard Law Department), all of whom had instructions that the report and associated materials were confidential and that any further distribution of the report should be limited to only those employees or consultants who need the report to perform their proper job functions." (R. Doc. 54-14 at 3).

Bard has also provided the court with the evidentiary hearing transcript held on June 11, 2014 in *Alexander v. Bard*, No. 3:12-cv-5187, before Magistrate Judge Harris Toliver of the Northern District of Texas. (R. Doc. 54-15).[12] In that hearing, Ms. Passero testified that starting in at least February of 2004 through November of that year, she received complaints, including demands for money, from individual patients, as well as attorneys regarding injuries and deaths allegedly caused by Bard's Recovery Filter, and that she was involved in responding to those

[12] This Evidentiary Hearing Transcript is attached to Bard's Motion as Exhibit Q. The transcript for the closed hearing is sealed in the *Alexander* action. *See Alexander*, No. 3:12-cv-5187, ECF No. 115. The *Alexander* court granted permission to counsel for the parties in that action to use the sealed hearing transcript in other actions to aid courts in determining whether the Lehmann Report is protected from discovery. *Alexander*, No. 3:12-cv-5187, ECF Nos. 124, 125. Although this document was filed under seal, it is referenced and quoted extensively in Bard's Motion, which was not filed under seal. (*See* R. Doc. 33-1 at 6-8, 10, 13-14, 18). The court's review confirms that the *Alexander* Evidentiary Hearing Transcript is consistent with the representations made in Bard's Motion. The substance of the *Alexander* Evidentiary Hearing Transcript is also discussed and quoted in previous decisions. *See Jones*, No. 13-cv-599, at *3-5, 12; *Alexander*, No. 12-cv-5187, at *4-5, 12.

complaints. (*See* R. Doc. 54-15 at 20-24, 36). Ms. Passero testified that "the fact of there being deaths would have immediately raised my concern . . . you would almost expect to have a lawsuit out of a death." (R. Doc. 54-15 at 24). In response to receiving these letters, Ms. Passero notified Bard's insurance carrier about potential lawsuits because she expected Bard to be sued when a patient's death is at issue. (R. Doc. 54-15 at 24). Further, Ms. Passero testified that when she and Bard's law department retained Dr. Lehmann in November of 2004, there had possibly been between five and ten deaths, and Ms. Passero and Bard's new general counsel needed to advise senior management and the board of directors regarding the company's exposure and risk, which is why they retained Dr. Lehmann. (R. Doc. 54-15 at 26-27). Ms. Passero testified that, to that end, Bard wanted Dr. Lehmann to compare its product to other similar products in the marketplace and to learn what experts were saying about Bard's product so they could use that information to devise the necessary advice. (R. Doc. 54-15 at 27-28). Ms. Passero answered "No" when asked "Would you have retained Dr. Lehmann to prepare this report in December 2004 if you had not had threats of litigation at that time?" (R. Doc. 54-15 at 33). Finally, Ms. Passero testified that after the Lehmann Report was submitted, Bard's Product Assessment Team was permitted to use the Lehmann Report in connection with the drafting of the RAP, but the Lehmann Report was drafted exclusively for Bard's Law Department and not as part of Dr. Lehmann's job as a member of the Product Assessment Team. (R. Doc. 54-15 at 72-75).

In spite of the foregoing, and the overwhelming majority of decisions concluding that the Lehman Report is work product, the Petersons argue that Bard's primary motivating purpose for creating the Lehmann Report was not anticipation of litigation. The Petersons argue that throughout 2004, Bard was investigating the adverse events of the Recovery Filter (which Bard

does not deny) and theorizes that "Bard strategically attempted to rewrite history by cloaking the final Lehmann report from potential discovery by funneling it through the law department under a separate yet parallel contract with Dr. Lehmann." (R. Doc. 41-1 at 12). In short, the Petersons argue that the RAP relied exclusively on Dr. Lehmann's analysis and, therefore, the Lehmann Report was assembled in the ordinary course of business or otherwise pursuant to a public requirement unrelated to litigation. (R. Doc. 41-1 at 13-15) (citing *United States v. El Paso Co.*, 682 F.2d 530, 542 (5th Cir. 1982)).

Having considered the foregoing evidence and arguments, the court concludes the Lehmann Report is work product. The analysis from the *Jones* and *Alexander* decisions from the Northern District of Texas is particularly persuasive, as those decisions applied the controlling "primary motivating purpose" standard of the Fifth Circuit in finding that the Lehman Report is work product. *See Jones*, No. 13-cv-599, at *12-14; *Alexander*, No. 12-cv-5187, at *11-14; *but see Tillman*, No. 13-cv-222, at *11 (finding that the Lehmann Report was not work product pursuant to the "primary motivating purpose" standard). This court agrees with the *Jones* and *Alexander* decisions that the primary motivating purpose for the creation of the Lehmann Report was to aid in potential litigation.

As discussed above, Ms. Passero has averred in her affidavit and testimony in the *Alexander* hearing that Dr. Lehmann was retained by Bard's Legal Department to provide an analysis of the Recovery Filter in light of complaints regarding that IVC filter failure and demands for money. The Lehman Report, which the court has reviewed *in camera*, is labeled "privileged and confidential – attorney work product" at the top of each page. Although this court has not conducted an *in camera* inspection of the contract leading to the creation of the Lehman Report, the *Jones* and *Alexander* courts have determined that it supports a finding that

the Lehman Report was created in anticipation of litigation and is work product. *See Jones*, No. 13-cv-599, at *13; *Alexander*, No. 12-cv-5187, at *12. The involvement of counsel in the preparation of the Lehman Report is a "highly relevant fact" in favor of finding that the primary motivating purpose in creating the document was anticipated litigation. *Carroll*, 2006 WL 1793656, at *2; *see also Kansas City Southern Ry. Co. v. Nichols Const. Co., L.L.C.*, No. 05-cv-1182, 2007 WL 2127820, **3-6 (E.D. La. July 25, 2007) (involvement of attorney by insurance carrier on the day of an accident favored finding that investigative materials from the day of the accident forward were created in anticipation of litigation). Furthermore, the evidence before the court suggests that the Lehman Report was created in response to alleged adverse effects (including deaths) resulting from the implantation of Bard's Recovery Filter. Accordingly, the Lehman Report was created "in response to a particular circumstance" that supports a finding that the document is work product. *See Transocean Deepwater, Inc. v. Ingersoll-Rand Co.*, No. 08-cv-4448, 2010 WL 5374744, *3 (E.D. La. Dec. 21, 2010) (finding that severity of the injury coupled with involvement of attorney in drafting Root Cause Analysis Report qualified as a particular circumstance that supported conclusion that document was created in anticipation of litigation).

There is a "chronological problem" with Plaintiff's position that the report was generated for business purposes in light of its incorporation into the RAP. *See Jones*, No. 13-cv-599, at *12; *Alexander*, No. 12-cv-5187, at *11; *Carr*, 297 F.R.D. at 332. This position wrongly focuses on subsequent uses of the Lehmann Report, as opposed to the initial purpose for which the document was created. The subsequent provision of this document to the Product Assessment Team, its attachment to the RAP, and use for the HHE does not bear upon the actual purpose for the Lehmann Report's creation. *See Jones*, No. 13-cv-599, at *13-14; *Alexander*, No. 12-cv-599,

at *12-13. Furthermore, that some employees have testified that they believed the Lehmann Report was commissioned for non-legal reasons does not alter the Lehmann Report's status as protected work product.

Bard has met its burden of providing that the "primary motivating purpose" of the creation of the Lehmann Report was to aid in anticipated litigation and the Lehmann Report is therefore work product.

B. Whether Plaintiffs have a Substantial Need for the Lehmann Report

Having concluded that the Lehmann Report is protected work product, the court will turn to whether Plaintiffs have a substantial need for the document. The Lehman Report is subject to discovery if Plaintiffs can show that that the document is "otherwise discoverable" and that Plaintiffs have a "substantial need for the materials to prepare [their] case and cannot, without undue hardship, obtain the [Lehmann Report's] substantial equivalent by other means. Federal Civil Rule 26(b)(3)(A)(i) and (ii). The Petersons must not only show that the Lehmann Report is relevant, but must also show that the Lehmann Report is sufficiently unique and important, as compared to other possible sources of the same information, to justify overriding work product protection.

The Lehmann Report would be discoverable in the absence of work product protection. The Petersons have established that Bard represented to the FDA that the G2 Filter is substantially identical to the Recovery Filter, the subject of the Lehmann Report. The Lehmann Report contains information relevant to the Petersons' claim that the G2 Filter contains design flaws.

The Petersons have failed to demonstrate, however, that they have a substantial need for the Lehmann report to prepare their case and cannot obtain a "substantial equivalent" by other

means without undue hardship. The Petersons have access to, and can use, the Lehmann Report's "source" data, including data found on the MAUDE database, to generate a similar analysis of Recovery Filter failures.[13] Furthermore, the Petersons have access to the RAP and the HHE, which incorporate analysis from the Lehmann Report. Indeed, the Petersons represent that "those regulatory documents were based entirely on the content" of the Lehmann Report. (R. Doc. 41-1 at 17). Accordingly, the Petersons can obtain "substantial equivalent" to the Lehmann Report, without undue hardship, by (1) discovering the source materials used in the Lehmann Report and (2) obtaining publicly available documents that incorporate the analysis found in that report.[14]

Consistent with rulings by other federal courts to have considered this very issue, the Petersons have not demonstrated that, despite being protected by the work product doctrine, they should have access to the Lehmann Report on the basis of substantial need and inability to obtain a substantial equivalent to the Lehmann Report without undue burden. *See Jones*, No. 13-cv-599, at *15 ("[T]he undersigned finds that Plaintiff has access to the same data as Dr. Lehmann. Therefore, he can obtain the substantial equivalent of the Lehmann Report by other means and without undue hardship"); *Alexander*, No. 12-cv-5187, at *14 (same); *Carr*, 297 F.R.D. at 334 (holding that the plaintiff did not show a substantial need for the Lehmann Report where the data underlying the report already had been disclosed in other public documents, and the patient could investigate Bard's awareness of any failures of the medical device by deposing quality control and management employees); *Phillips*, 290 F.R.D. at 671 (holding that the plaintiff did not show

[13] Bard represents that the Petersons have produced an expert report by Dr. Michael Freeman "who purports to recreate Dr. Lehmann's analysis." (R. Doc. 49 at 8).

[14] The Petersons clearly would like to be able to use the Lehmann Report as evidence to demonstrate Bard's own analysis of the Recovery Filter's failure rates. This desire alone "does not demonstrate substantial need for the Lehmann Report, much less that equivalent evidence could not be generated except with undue hardship." *Carr*, 297 F.R.D. at 334 (*citing Phillips*, 290 F.R.D. at 671).

a substantial need for the Lehmann Report where he had various other avenues for gathering the information he sought to support his claim); *Ebert*, 2014 WL 1632155, at *4-5 (holding that the plaintiff had not shown a substantial need for the Lehmann Report because she had access to Bard's RAP and HHE, which were created using the information contained in the Lehmann Report).

C. Whether Bard Waived the Work Product Doctrine

The Petersons also argue that even if the Lehmann Report is work product, that protection has been lost through waiver. The Petersons' factual basis for claiming waiver is that "David Ciavarella, MD, (Bard's former Medical Director), Brian Hudson (a Bard Engineer), Brian Barry (V.P. of Regulatory Affairs) and Robert Carr (Director of Research and Development) have all testified that they were given copies of the document at issue in the ordinary course of business." (R. Doc. 41-1 at 17-18) (citing deposition transcripts).[15] The Petersons also suggest that Dr. Ciavarella's discussion of the Lehmann Report at a Bariatric Surgeons Panel conference on February 12, 2005 led to waiver of any work product production. (R. Doc. 41-1 at 18).

Notably, the Petersons do not cite case law concerning the waiver of the work product doctrine. Instead, the Petersons rely on a Fifth Circuit decision discussing waiver of the attorney-client privilege—"voluntary disclosure of information which is inconsistent with the confidential nature of the attorney client relationship." *Alldread v. City of Grenada*, 988 F.2d 1425, 1434 (5th Cir. 1993).

[15] The Petersons further state that "Dr. Ciavarella, Mr. Barry and Mr. Hudson were not told to keep this document confidential or that it was in anticipation of the defense of any litigation." (R. Doc. 41-1 at 18) (citing deposition transcripts).

This "voluntary disclosure" argument must be rejected. As explained by the Fifth Circuit:

> The work product privilege is very different from the attorney-client privilege. The attorney-client privilege exists to protect confidential communications and to protect the attorney-client relationship and is waived by disclosure of confidential communications to third parties. The work product privilege, however, does not exist to protect a confidential relationship but to promote the adversary system by safeguarding the fruits of an attorney's trial preparations from the discovery attempts of an opponent. Therefore, the mere voluntary disclosure to a third person is insufficient in itself to waive the work product privilege

Shields v. Sturm, Ruger & Co., 864 F.2d 379, 382 (5th Cir. 1989) (citations omitted). Accordingly, that Bard may have voluntarily disclosed information from the Lehmann Report to third-parties (be it through the RAP, the HHE, or at the Bariatric Surgeons Panel) is an insufficient basis for waiving the protections provided by the work product doctrine. Moreover, by providing the documents to other high-level employees, Bard's Law Department did not waive the protections afforded by the work product doctrine. The Petersons have simply not demonstrated that the Lehmann Report was voluntarily provided to an adversary of Bard in such a way that would constitute a waiver of the work product doctrine.[16]

III. Conclusion

In sum, the court concludes the Lehmann Report is work product because Bard's primary motivating purpose for the creation of the document was anticipation of litigation. The Petersons have failed to make the showing necessary to overcome work product protection or to demonstrate that Bard has waived work product protection.

[16] The Petersons have not argued that Bard has waived the work product doctrine through inadvertent disclosure or at-issue waiver.

IT IS ORDERED THAT Defendants' Motion for Protective Order Regarding Discovery of Litigation Consultant's Report (R. Doc. 33) is **GRANTED**. The Lehman Report may not be used or obtained through discovery in this matter.

Signed in Baton Rouge, Louisiana, on March 3, 2015.

RICHARD L. BOURGEOIS, JR.
UNITED STATES MAGISTRATE JUDGE

EXHIBIT E

Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism

Clement J. Grassi, MD, Timothy L. Swan, MD, John F. Cardella, MD, Steven G. Meranze, MD, Steven B. Oglevie, MD, Reed A. Omary, MD, Anne C. Roberts, MD, David Sacks, MD, Mark I. Silverstein, MD, Richard B. Towbin, MD, and Curtis A. Lewis, MD, MBA, for the SCVIR Standards of Practice Committee

Index terms: Embolism, pulmonary • Standards of practice • Venae cavae, filters

J Vasc Interv Radiol 2001; 12:137–141

Abbreviations: IVC = inferior vena cava, PE = pulmonary embolism

PULMONARY embolism (PE) continues to be a major cause of morbidity and mortality in the United States. Estimates of the incidence of nonfatal PE range from 400,000 to 630,000 cases per year, and 50,000 to 200,000 fatalities per year are directly attributable to PE (1–4). The current preferred treatment for deep venous thrombosis and PE is anticoagulation therapy. However, as many as 20% of these patients will have recurrent PE (1,5,6).

Interruption of the inferior vena cava (IVC) for the prevention of PE was first performed in 1893 with use of surgical ligation (7). Over the years, surgical interruption took many forms (ligation, plication, clipping, or stapling) but IVC thrombosis was a frequent complication after these procedures. Endovascular approaches to IVC interruption became a reality in 1967 after the introduction of the Mobin-Uddin filter (8).

Many devices have since been developed for endoluminal caval interruption but, currently, there are six devices commercially available in the United States. These devices are designed for permanent placement. For detailed information regarding each of these filters, the reader is referred to several published reviews (9–12). Selection of a device requires knowledge of the clinical settings in which filters are used, evaluation of the clot trapping efficiency of the device, occlusion rate of the IVC and access vein, risk of filter migration, filter embolization, structural integrity of the device, and ease of placement.

Percutaneous caval interruption can be performed as an outpatient or inpatient procedure. However, practically speaking, most filter placements will occur in the inpatient population because of ongoing medical therapy for acute thromboembolic disease or underlying illness.

The IVC should be assessed with imaging before placement of a filter and the current preferred imaging method is vena cavography. Before filter selection and placement, the infrarenal IVC length and diameter should be measured, the location and number of renal veins determined, IVC anomalies (eg, duplication) defined, and intrinsic IVC disease such as preexisting thrombus or extrinsic compression excluded. The ideal placement for the prevention of lower extremity and pelvic venous thromboembolism is the infrarenal IVC. The apex or superior aspect of any filtration device should be at or immediately inferior to the level of the renal veins according to the manufacturers' recommendations. In specific clinical circumstances, other target locations may be appropriate.

Percutaneous caval interruption is commonly accomplished through right femoral and right internal jugular vein approaches; however, other peripheral and central venous access sites can be used. Filters can be placed in veins other than the vena cava to prevent thromboembolism. Implant sites have included iliac veins, subclavian veins, superior vena cava, and IVC (suprarenal and infrarenal). This document will provide quality improvement guidelines for filter placement within the inferior vena cava because of the limited data available for implantation sites other than the IVC. The patient's clinical condition, the type of filter available, the alternative access sites available, and the expertise of the treating physician should always be considered when the decision to place an IVC filter has been made.

These guidelines are written to be used in quality improvement programs to assess percutaneous interruption of the IVC to prevent pulmonary embolism. The most important processes of care are (i) patient selection, (ii)

A complete list of the members of the SCVIR Standards of Practice Committee is given at the end of this article. **Address correspondence to** C.J.G., Department of Radiology, Brigham & Women's Hospital, 75 Francis St., Boston, MA 02115-6110.

performing the procedure, and (iii) patient monitoring. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

DEFINITIONS

Procedural Success: Deployment of a filter such that the filter is judged suitable for mechanical protection against PE.

Procedural Failure: The procedure concludes with unsatisfactory filter deployment such that the patient has inadequate mechanical protection against PE.

Death: Procedurally related death directly attributable to the filter itself documented by clinical findings, imaging, or autopsy.

Recurrent PE: Pulmonary embolism occurring after filter placement documented by pulmonary arteriography, cross sectional imaging, altered ventilation-perfusion lung scan to high probability of PE, or autopsy.

IVC Occlusion: Presence of an occluding thrombus in the IVC occurring after filter insertion and documented by US, CT, MR imaging, venography, or autopsy.

IVC Penetration: Penetration of the vein wall by filter hooks with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration is filter strut or anchor devices extending more than 3 mm outside the wall of the IVC demonstrated by CT, US, venography, or autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (see below).

Filter Embolization: Post-deployment movement of the filter to a distant anatomic site completely out of the target zone.

Migration: Filter migration defined as a change in filter position compared to its deployed position (either cranial or caudal) more than 2 cm as documented by plain film imaging, CT, or venography.

Filter Fracture: Any loss of structural integrity (ie, breakage or separation) of the filter documented by imaging or autopsy.

Insertion Problems: Filter or deployment system related malfunctions such as incomplete filter opening, filter tilt more than 15° from the IVC axis (eg, non–self-centering filters), misplacement of filter outside of the infrarenal IVC when the operators' intent is to place the filter in the infrarenal IVC (eg, when a portion of the filter is within one iliac vein), or prolapse of filter components. Filter malposition requiring surgical removal is considered an insertion problem complication.

Access Site Thrombus: Occlusive or nonocclusive thrombus developing after filter insertion at the venotomy site (13–17).

Other access site complications with clinical sequelae: Arteriovenous fistula, hematoma, or bleeding requiring a transfusion, hospitalization (either admission or extended stay), or further treatment for management.

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold a review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in: admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix 1. The complication rates and thresholds listed herein refer to *major* complications.

INDICATIONS

Accepted

1. Patients with evidence of pulmonary embolus or IVC, iliac, or femoral-popliteal deep venous thrombosis and one or more of the following (13–16):
   a. Contraindication to anticoagulation
   b. Complication of anticoagulation
   c. Failure of anticoagulation
      i. Recurrent PE despite adequate therapy
      ii. Inability to achieve adequate anticoagulation
2. Massive pulmonary embolism with residual deep venous thrombus in a patient at risk for further PE
3. Free-floating iliofemoral or IVC thrombus
4. Severe cardiopulmonary disease and deep venous thrombosis (eg, cor pulmonale with pulmonary hypertension)
5. Poor compliance with anticoagulant medications

Additional Indications For Selected Patients

1. Severe trauma without documented PE or deep venous thrombosis
   a. Closed head injury
   b. Spinal cord injury
   c. Multiple long bone or pelvic fractures
2. High-risk patients (eg, immobilized, intensive care patients, prophylactic preoperative placement in patients with multiple risk factors for venous thromboembolism)

Suprarenal Filter Placement

1. Renal vein thrombosis
2. IVC thrombosis extending above the renal veins
3. Filter placement during pregnancy; suprarenal placement is also appropriate in women of childbearing age
4. Thrombus extending above previously placed infrarenal filter

Table 1
Complications

Complications	Reported Rates (%)	Threshold (%)
Death (7)	0.12	<1
Recurrent PE (17–22)	0.5–6	5
IVC Occlusion (11,17,19,20,23–27)	2–30	10
Filter Embolization (17,24,28–37)	2–5	2
Access Site Thrombosis—Major (see Appendix 1) (38,39)	0–6*	1

* Includes reported rates of both major and minor complications.

Table 2
Other Trackable Events

Other Trackable Events	Reported Rates (%)
IVC Penetration (7,17,19,23,27,40,52)*	0–41
Migration (7,9,10,17,19–21,26,41,42)*	0–18
Filter Fracture (17,24)	2–10
Access Site Thrombus	
All types (7,38,43,44)	0–25
Occlusive (38,45)	3–10
Insertion Problems (7,17,19–22,24,26,41,43,46,47)	5–50
Other complications (48,49)	1–15

Note.—The rate of clinically significant penetration is undefined in the literature (39,50,52).
* Clinically significant penetration and migration are believed to be rare.

5. Pulmonary embolism after gonadal vein thrombosis
6. Anatomic variants: duplicated IVC, low insertion of renal veins

RELATIVE CONTRAINDICATIONS (TO PERCUTANEOUS PLACEMENT)

1. Uncorrectable severe coagulopathy (eg, patients with liver or multisystem failure).
2. Caution should be exercised when placing a filter in patients with bacteremia or untreated infection; clinical judgement should be applied in these situations weighing the theoretical risk of implant infection versus the risk of PE.

For pediatric and young adult patients, filter placement indications should be strict because the long-term effects and durability of the devices are not precisely known.

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the department will review the process of patient selection.

SUCCESS

It is expected that the technical success for percutaneously placed IVC filters will be 97% or better in experienced hands. Therefore, the proposed threshold for review of technical failures should be 3%.

COMPLICATIONS

Each currently available filter has been studied extensively as part of the Food and Drug Administration approval process. Few comparative studies have been completed evaluating all filters in one project, and those that have done so have been retrospective analyses. Complication rates are highly variable depending on the filter being studied. For simplicity, these guidelines will not suggest threshold rates for each individual filter; rather, filtration devices will be considered as a group (**Table 1**).

Published rates for individual types of complications are highly dependent on patient selection and are, in some cases, based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to exceed a complication-specific threshold when the complication occurs in a small volume of patients, for example, early in a quality improvement program (18–52).

OTHER TRACKABLE EVENTS

Because an IVC filter is a permanent implantable device and because this device is sometimes placed in relatively young patients, several other trackable parameters when observed are appropriate to record in a quality improvement program. The events listed in **Table 2** may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

Acknowledgments: Clement Grassi, MD, and Timothy Swan, MD, authored the first draft of this document and served as topic leaders during the subsequent revisions of the draft. Dr. John Cardella is chair of the SCVIR Standards Committee. Curtis Lewis, MD, MBA, is Councilor of the SCVIR Standards Division. All other authors are listed alphabetically. Other members of the Standards of Practice Committee and SCVIR who participated in the development of this clinical practice guideline are John E. Aruny, MD, Curtis Bakal, MD, MPH, Dana Burke, MD, Paramjit Chopra, MD, Steven J. Citron, MD, Patricia E. Cole, PhD, MD, Martin Crain, MD, Andrew Davis, MD, Alain Drooz, MD, Elizabeth Drucker, MD, JD, Neil Freeman, MD, Jeff Georgia, MD, Richard Shlansky-Goldberg, MD, Richard Gray, MD, Sue Hanks, MD, Ziv Haskal, MD, James Husted, MD, Michael Todd Jones, MD, Patrick C. Malloy, MD, Louis Martin, MD, Timothy C. McCowan, MD, Theodore Mirra, MD, Sally Mitchell, A. Van Moore, MD, Calvin D. Neithamer, MD, Nilesh Patel, MD, Paravati Ramchandani, MD, Kenneth S. Rholl, MD, Orestes Sanchez, MD, Harjit Singh, MD, Bob Smouse, MD, Patricia Thorpe, MD, Scott Trerotola, MD, Anthony Venbrux, MD, and Daniel Wunder, MD.

APPENDIX 1: SCVIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. Result in no therapy, no consequence, or

B. Result in nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (<48 hours),

D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours),

E. Cause permanent adverse sequelae, or

F. Cause death

APPENDIX 2: METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from standards of practice committee member practices and, when available, the SCVIR HI-IQ system National Database. Consensus on statements in this document was obtained with use of a modified Delphi technique (53,54).

Technical documents specifying the exact consensus and literature review methodologies are available upon request from the Society of Cardiovascular & Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

References

1. Dalen F, Albert JS. Natural history of pulmonary emboli. Prog Cardiovas Dis 1975; 17:259–270.
2. Consensus Development Panel. Prevention of venous thrombosis and pulmonary embolism. JAMA 1986; 256: 744–749.
3. Goldhaber SZ, Hennekens CH, Evans DA, et al. Factors associated with correct antemortem diagnosis of major pulmonary embolus. Am J Med 1982; 73:822–826.
4. Clagett GP. Basic data related to venous thromboembolism. Ann Vasc Surg 1988; 2:402–405.
5. Silver D, Sabiston DC. The role of vena cava interruption in management of pulmonary embolism. Surgery 1975; 77:1–10.
6. Glenny RW. Pulmonay embolism. South Med J 1987; 80:1266–1276.
7. Becker DM, Philbrick JT, Selby JB. Inferior vena cava filters: indication, safety, effectiveness. Arch Intern Med 1992; 152:1985–1994.
8. Mobin-Uddin K, Smith PE, Martinez LO, Lombardo CR, Jude JR. A vena caval filter for the prevention of pulmonary embolus. Surg Forum 1967; 18: 209–211.
9. Grassi CJ. Inferior vena caval filters: analysis of five currently available devices. AJR Am J Roentgenol 1991; 156:813–821.
10. Dorfman GS. Percutaneous inferior vena caval filters. Radiology 1990; 174: 987–992.
11. Greenfield LJ, DeLucia A 3d. Endovascular therapy of venous thromboembolic disease. Surg Clin North Am 1992; 72:969–989.
12. Savader SJ. Inferior vena cava filters. In Savader SJ and Trerotola S (eds): Venous Interventional Radiology with Clinical Perspectives. Thieme, New York, NY 1996: 367–399.
13. Ray CE, Kaufman JA. Complications of inferior vena cava filters. Abdom Imaging 1996; 21:368–374.
14. Kaufman JA, Geller SG. Indications for vena cava filters. AJR Am J Roentgenol 1995; 164:256–257.
15. Valji K. Vascular and Interventional Radiology. Philadelphia: WB Saunders, 1999:305.
16. Norris C, Greenfield L, Hermanson J. Free-floating iliofemoral thrombus: a risk of pulmonary embolism. Arch Surg 1985; 120:806–808.
17. Ferris EJ, McCowan TC, Carver DK, McFarland DR. Percutaneous inferior vena caval filters: follow-up of seven designs in 320 patients. Radiology 1993; 188:851–856.
18. Greenfield LJ, Proctor MC. Twenty-year clinical experience with the Greenfield filter. Cardiovasc Surg 1995; 3:199–205.
19. Millward SF, Peterson RA, Moher D, et al. LGM (Vena-Tech) vena caval filter: experience at a single institution. J Vasc Interv Radiol 1994; 5:351–356.
20. Crochet DP, Stora O, Ferry D, et al. Vena Tech-LGM filter: long term results of a prospective study. Radiology 1993; 188:857–860.
21. Simon M, Athanasoulis CA, Kim D, et al. Simon nitinol inferior vena cava filter: initial clinical experience. Radiology 1989; 172:99–103.
22. Greenfield L, Cho KJ, Proctor M, et al. Results of a multicenter study of the modified hook-titanium Greenfield filter. J Vasc Surg 1991; 14:253–257.
23. Magnant JG, Walsh DB, Juravsky LI, Cronenwett JL. Current use of inferior vena cava filters. J Vasc Surg 1992; 16:701–706.
24. McCowan TC, Ferris EJ, Carver DK, Molpus WM. Complications of the nitinol vena cava filter. J Vasc Interv Radiol 1992; 3:401–408.
25. Hye RJ, Mitchell AT, Dory CE, Freischlag JA, Roberts AC. Analysis of the transition to percutaneous placement of Greenfield filters. Arch Surg 1990; 125:1550–1553.
26. Ricco JF, Crochet D, Sebilotte P, et al. Percutaneous transvenous caval interruption with "LGM" filter: early results of a multicenter trail. Ann Vasc Surg 1988; 3:242–247.
27. Lang W, Schweiger J, Hofmann-Preiss K. Results of long-term venacavography study after placement of a Greenfield vena caval filter. J Cardiovasc Surg 1992; 33:573–578.
28. Atkins CW, Thurer RL, Waltman AC, Margolies MN, Schneider RC. A misplaced caval filter: its removal from the heart without cardiopulmonary bypass. Arch Surg 1980; 115:1133–1135.
29. Casteneda F, Herrera M, Cragg AH, et al. Migration of a Kimray Greenfield filter to the right ventricle. Radiology 1983; 149:690–691.
30. Friedell ML, Goldenkranz RJ, Parsonnet V, et al. Migration of a Greenfield filter to the pulmonary artery: a case report. J Vasc Surg 1986; 3:929–931.
31. Urbaneja A, Fontaine AB, Bruckner M, Spigos DG. Evulsion of a vena tech filter during insertion of a central venous catheter. J Vasc Interv Radiol 1994; 5:783–785.
32. Loesberg A, Taylor FC, Awh MH. Dislodgment of inferior vena caval filters during blind insertion of central venous catheters. AJR Am J Roentgenol 1993; 161:637–638.
33. Puram B, Maley TJ, White NM, Rotman HH, Miller G. Acute myocardial infarction from the migration of a Greenfield filter. Chest 1990; 98:1510–1511.
34. Bach JR, Zaneuski R, Lee H. Cardiac arrhythmias from malpositioned Greenfield filter in a traumatic quadriplegic. Am J Phys Med Rehabil 1990; 69:251–253.
35. Villard J, Detry L, Clermont A, Pinet F. Eight cases of Greenfield filters in the right heart cavities: their surgical treatment. Ann Radiol 1987; 30:102–104.
36. LaPlante JS, Contractor FM, Kiproff PM, Khoury MB. Migration of the Simon nitinol vena cava filter to the chest. AJR Am J Roentgenol 1993; 160: 385–386.

37. 37.Poillaud C, Ollitraut J, Paillard F, Biron Y, Gouffault J. Proximal migration of a caval filter: apropos of a case. Ann Cardiol Angeiol (Paris) 1988; 37: 129–13140.
38. Molgaard CP, Yucel EK, Geller SC, Knox TA, Waltman AC. Access-site thrombosis after placement of inferior vena cava filters with 12–14 F delivery sheaths. Radiology 1992; 185:257–261.
39. Blebea J, Wilson R, Waybill P, et al. Deep venous thrombosis after percutaneous insertion of vena caval filters. J Vasc Surg 1999; 30:821–829.
40. Athanasoulis CA. Complications of vena cava filters. Radiology 1993; 188: 614–615.
41. Murphy TP, Dorfman GS, Yedlicka JW, et al. LGM vena cava filter: objective evaluation of early results. J Vasc Interv Radiol 1991; 2:107–115.
42. Vesely TM. Technical problems and complications associated with inferior vena cava filters. Sem Intervent Radiol 1994; 11:121–133.
43. Sweeney TJ, Van Aman ME. Deployment problems with the titanium Greenfield filter. J Vasc Interv Radiol 1993; 4:691–694.
44. Millward SF, Marsh JI, Peterson RA, et al. LGM (Vena Tech) vena cava filter: clinical experience in 64 patients. J Vasc Interv Radiol 1991; 2:429–433.
45. Hicks ME, Middleton WD, Picus D, Darcy MD, Kleinhoffer MA. Prevalence of local venous thrombosis after transfemoral placement of a Bird's Nest vena caval filter. J Vasc Interv Radiol 1990; 1:63–68.
46. Moore BS, Valji K, Roberts AC, et al. Transcatheter manipulation of asymmetrically opened titanium Greenfield filters. J Vasc Interv Radiol 1993; 4:687–690.
47. Teitelbaum GP, Jones DL, van Breda A, et al. Vena caval filter splaying: potential complication of use of the titanium Greenfield filter. Radiology 1989; 173:809–814.
48. Grassi CJ, Bettmann MA, Rogoff P, Reagan K, Harrington DP. Femoral arteriovenous fistula after placement of a Kimray-Greenfield filter. AJR Am J Roentgenol 1988; 151:681–682.
49. Iuanow E, Kandarpa K, Chopra R, Grassi CJ. Bleeding complications in patients undergoing percutaneous vena cava filter placement using new low profile introduction systems. Presentation at: American Roentgen Ray Annual Meeting; April 1993; San Francisco, CA. p27.
50. Appleberg M, Crozier JA. Duodenal penetration by a Greenfield caval filter. Aust N Z J Surg 1991; 61:957–960.
51. Howerton RM, Watkins M, Feldman L. Late arterial hemorrhage secondary to a Greenfield filter requiring operative intervention. Surgery 1991; 109:265–268.
52. Simon M. Vena cava filters: prevalent misconceptions. J Vasc Interv Radiol. 1999; 10:1021–1024.
53. Fink A, Kosefcoff J, Chassin M, Brook RH, Consensus methods: characteristics and guidelines for use. Am J Public Health 1984; 74:979–983.
54. Leape LL, Hilborne LH, Park RE, et al. The appropriateness of use of coronary artery bypass graft surgery in New York State. JAMA 1993; 269:753–760.

EXHIBIT F

BARD
PERIPHERAL
VASCULAR

October 5, 2004

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-410)
9200 Corporate Boulevard
Rockville, MD 20850

ATTN: Lisa M. Kennell

Re: Additional Correspondence: Bard® Recovery® Filter System RF-048F
K031328

Dear Ms. Kennell:

Pursuant to our conversation of September 28, 2004, attached is additional correspondence regarding changes to the **Bard Recovery Filter System** Information for Use. Included in this correspondence are the 1) new proposed labeling, 2) a red-lined revision of the previous IFU, 3) a copy of correspondence intended to inform clinicians of the proposed modifications, and 4) a chart of possible and reported adverse events for the **Bard Recovery Filter System**, adverse event rates based on sales, and lastly, the complication and trackable event rates according to the most recent *Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for Prevention of Pulmonary Embolism* according to the SIR Standards of Practice Committee as published in the Journal of Vascular Interventional Radiology, 2003; 14S271-S275. **Please note that these proposed modifications do not change the original intended use, indications or contraindications of the Bard Recovery Filter System.**

Bard Peripheral Vascular, Inc. wishes this version of the Information for Use be placed in the above-referenced file.

Bard Peripheral Vascular has not publicly disclosed or acknowledged the existence of this correspondence to any individual outside its employ other than disclosure made under commercial agreements containing the appropriate safeguards for secrecy. As a result, Bard Peripheral Vascular requests that FDA keep and maintain confidential both the existence and the contents of the information in accordance with 21 CFR 812.38(a). Bard Peripheral Vascular also requests that FDA keeps and maintains confidential the contents of this letter.

If you have any questions or comments regarding this submittal, please contact me directly via telephone at 480-303-2640, facsimile at 480-449-2546 or via e-mail at mary.edwards@crbard.com.

Sincerely,

Mary Edwards
Vice-President
Regulatory and Clinical Affairs

Enclosures: Draft Information for Use, Red-lined Current Information for Use, Draft Customer Communication, Complication/Trackable Event Comparison Chart and Quality Improvement Article

1625 West 3rd Street • P. O. Box 1740 • Tempe, AZ 85280-1740
Tel: 1-800-321-4254 • 1-480-894-9515 • Fax: 1-480-966-7062 • www.bardpv.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: September 30, 2004.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
10/9/2004	Not applicable - Additional information for 510(k)	K031328

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (120 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name C. R. Bard, Inc.		Establishment Registration Number *(if known)* 2020394	
Division Name *(if applicable)* Bard Peripheral Vascular		Phone Number *(including area code)* (480) 303-2640	
Street Address 1415 West 3rd Street; P. O. Box 1740		FAX Number *(including area code)* (480) 449-2546	
City Tempe	State / Province AZ	ZIP/Postal Code 85280-1740	Country USA
Contact Name Mary J. Edwards			
Contact Title Vice-President		Contact E-mail Address mary.edwards@crbard.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

BPV-15-01-00058084

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify)*:
  Revision to IFU and communication to customers

BPV-15-01-00058085

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DTK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K031328	1	Recovery Filter System	1	C. R. Bard
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Intravascular Filter

	Trade or Proprietary or Model Name for This Device		Model Number
1	Recovery Filter System	1	RF-048F
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K031328	2 K022236	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
DTK	21 CFR 870.3375	☐ Class I ☐ Class II ☒ Class III ☐ Unclassified
Classification Panel: Cardiovascular		

Indications *(from labeling)*

The Recovery Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated
- Recovery filter may be removed according to the instructions supplied in the Section labeled: Optional Procedure for Filter Removal.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H **MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP Code	Country
ontact Name	Contact Title		Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

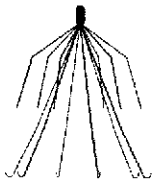
Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

DRAFT INFORMATION FOR USE

Recovery® Filter System for use in the Vena Cava



ENGLISH

Information for Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The ***Recovery*** Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the ***Recovery*** Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheath and release the filter and allow it to recover to its predetermined shape. The centering system allows the ***Recovery*** Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing while allowing for device removal when clinically indicated.

The ***Recovery*** Filter is designed to act as a permanent filter. When clinically indicated, the ***Recovery*** Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The ***Recovery*** Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (See Optional Removal Procedure for specific removal instructions).

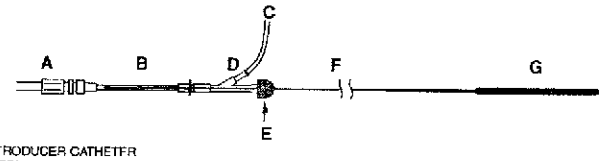
MRI Compatible: The ***Recovery*** Filter implant is MRI-safe and neither interferes with nor is affected by the operations of a MRI device.

B. Device Description

The ***Recovery*** Filter System consists of the filter and delivery system. The ***Recovery*** Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The ***Recovery*** Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The ***Recovery*** Filter Delivery System is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the ***Recovery*** Filter, a storage tube with saline infusion port, and a pusher system. The ***Recovery*** Filter is packaged pre-loaded within the delivery storage tube.

Figure A. Recovery Filter System



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the ***Recovery*** Filter

C. Indications for Use

The ***Recovery*** Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- ***Recovery*** Filter may be removed according to the instructions supplied below under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The *Recovery* Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

***Recovery* Filter Implantation**

1. The ***Recovery*** Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the ***Recovery*** Filter cannot be safely reloaded into the storage tube.
2. Do not deploy the filter unless IVC has been properly measured.
3. Delivery of the ***Recovery*** Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter.
4. The ***Recovery*** Filter System is designed for femoral approaches only. Never use the ***Recovery*** Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper ***Recovery*** Filter orientation within the IVC.
5. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.
6. Only use the ***Recovery Cone*** Removal System to remove the ***Recovery*** Filter. Never re-deploy a removed filter.
7. Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.
8. Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
9. Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.

See **Potential Complications** section for further information regarding other known filter complications.

***Recovery* Filter Removal**

1. Do not attempt to remove the ***Recovery*** Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena caval wall.
2. Use only the Bard ***Recovery Cone*** Removal System (packaged separately) to retrieve the ***Recovery*** Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.

F. Precautions

***Recovery* Filter Implantation**

1. The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age.
2. Anatomical variances may complicate filter insertion and deployment. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
3. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
4. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
5. If misplacement or sub-optimal placement of the filter occurs, consider immediate retrieval. Retrieve the ***Recovery*** Filter using the ***Recovery Cone*** Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
6. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
7. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
8. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
9. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
10. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
11. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
12. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer catheter.

***Recovery* Filter Removal**

1. Anatomical variances may complicate insertion and deployment of the ***Recovery Cone*** Removal System. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the ***Recovery*** Filter with the ***Recovery Cone*** Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage.
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear.
- Stenosis at implant site.

All these above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One ***Recovery*** Filter and Delivery System that contains:

  -One 48 cm, 7 French I.D. introducer catheter and dilator set

-One storage tube with pre-loaded *Recovery* Filter and pusher delivery system

- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

If the physician chooses to percutaneously remove the *Recovery* Filter, the *Recovery Cone* Removal System is available from C. R. Bard, Inc.

I. Instructions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

NOTE: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

NOTE: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

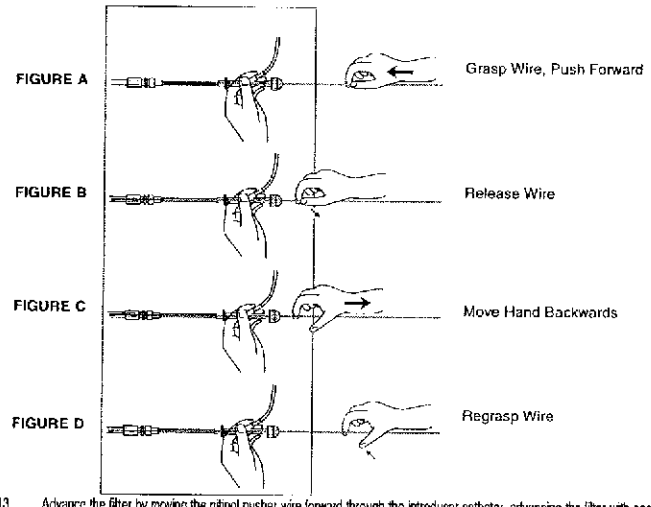
NOTE: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
10. Remove the filter and delivery system from Kit B.
11. Connect a 500-mL bag of saline to the sideport of the Y-adapter using a standard drip infusion set. Allow the saline infusion to flow around the filter in the storage tube for 5 seconds to soften it for passage through the introducer catheter. Adjust the infusion set to provide a rapid drip rate. Tighten the Touhy-Borst adapter valve to minimize reflux of saline, but not so tight as to prevent the pusher wire from advancing freely.

NOTE: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

12. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein, allowing the saline infusion to flow into the IVC for a few seconds. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.

Advancement of Filter, Illustrated

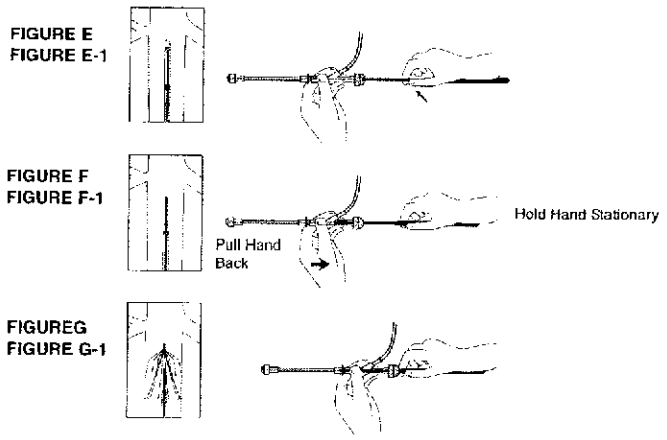


13. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.
14. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

Filter Release/Deployment

15. Deliver and release filter as described below:
    Figure E: Firmly hold the pusher wire handle.
    Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

Filter Release, Illustrated



NOTE: Do not deliver the filter by pushing it beyond the end of the introducer catheter. Instead, unsheath the stationary filter by withdrawing the introducer catheter as described below.

Position the filter tip 1 cm below the lowest renal vein.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter.

Figure F-1: Unsheathing of filter in IVC.
Figure G: The position of the hands at the completion of the unsheathing process.
Figure G-1: The filter deployed in the IVC.

16. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire.
17. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

CAUTION: Remove the *Recovery* Filter using the *Recovery Cone* only.

18. A follow-up venacavogram must be performed after withdrawing the introducer catheter into the iliac vein (typically 30 mL of contrast medium at 15 mL/s).
19. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Removal of *Recovery* Filter

Equipment Required

The following equipment is required for use:

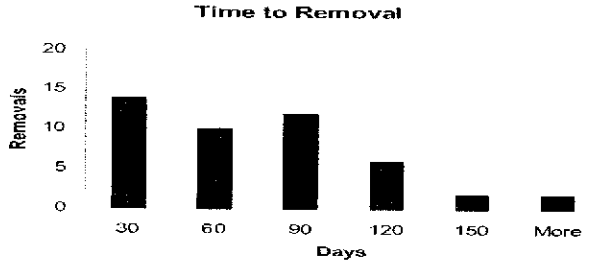
- One *Recovery Cone* Removal System that contains:
  -One 75 cm, 10 French I.D. introducer catheter and dilator set
  -One Y-adapter with *Recovery Cone* and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience

The *Recovery* Filter has been used in Canada by a single investigator and two colleagues at six Toronto-area hospitals in 58 subjects, under the Special Access regulations.

Although only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place from causes unrelated to filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, with an average of 60 days (see histogram below).



Follow up post retrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein (n=1). One filter was removed surgically during a cancer operation where the mass was impinging on the filter. The two methods described in the Instructions for Use section were used to retrieve the filter in all but 4 cases, when a larger sheath was used, or a snare loop was attempted instead of using the *Recovery Cone* removal system. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.

Clinical Experience 5	
Recovery Filters Implanted	58
Percutaneous Filter Removals	45
Surgical Filter Removals	1 (Concurrent to tumor resection)
Patient Age	8-89 years (52 years average)

Reason for Filter	
Contraindication to anticoagulation	40
Complications associated with anticoagulation	13
Failure of anticoagulation	3
Prophylaxis	2
Time to removal	1-161 days (60 days average)
Follow-up post-removal	1-901 days (325 average)

Filter Removal Complications	
Technical	0
Hook fracture secondary to stresses due to labor and birth and infrarenal placement	1
Asymptomatic pulmonary embolism post-removal	1

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone*** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the ***Recovery*** Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the ***Recovery*** Filter.

***Recovery Cone* Insertion and Delivery**

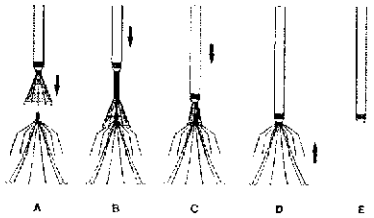
11. Remove the ***Recovery Cone*** and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone.

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the ***Recovery Cone*** in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
15. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
16. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
17. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheath to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of *Recovery* Filter

Filter Removal, Illustrated



18. The capture of the ***Recovery*** Filter is illustrated in Figures A-E:

Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

19. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

20. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
21. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the ***Recovery*** Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the ***Recovery*** Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.

Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 18.

J. How Supplied

Each ***Recovery*** Filter is supplied preloaded in a storage tube. Each ***Recovery*** Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

Note: After use, the *Recovery* Filter Delivery System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The ***Recovery*** Filter should be stored in a cool (room temperature), dry place.

K. Warranty

Bard warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

Labeling Issue Date: 10/04

In the event 3 years have elapsed between this date and product use, the user should contact C. R. Bard, Inc. to see if additional product information is available.

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.

Bard Peripheral Vascular, Inc.
P.O. Box 1740
Tempe, AZ 85280-1740
USA

CE 0086

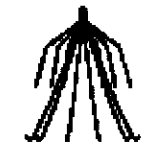
EEA Authorized Representative
Bard Limited
Crawley, UK
RH11 9BP

TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-966-7062
1-800-440-5376
www.bardpv.com

Red-Line Current
Information for Use

RED-LINED CURRENT INFORMATION FOR USE

Recovery® Filter System for use in the Vena Cava



ENGLISH

Information for Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The **Recovery** Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the **Recovery** Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheath and release the filter and allow it to recover to its predetermined shape. The centering system allows the **Recovery** Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing while allowing for device removal when clinically indicated.

The **Recovery** Filter is designed to act as a permanent filter. When clinically indicated, the **Recovery** Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The **Recovery** Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (See Optional Removal Procedure for specific removal instructions).

MRI Compatible: The **Recovery** Filter implant is MRI-safe and neither interferes with nor is affected by the operations of a MRI device.

B. Device Description

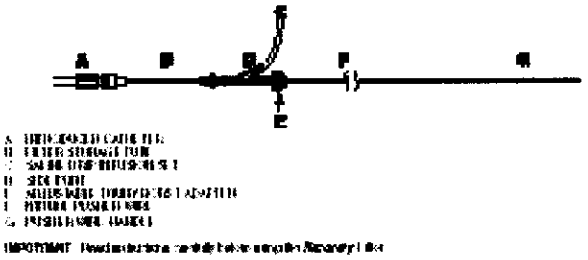
The **Recovery** Filter System consists of the filter and delivery system. The **Recovery** Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the

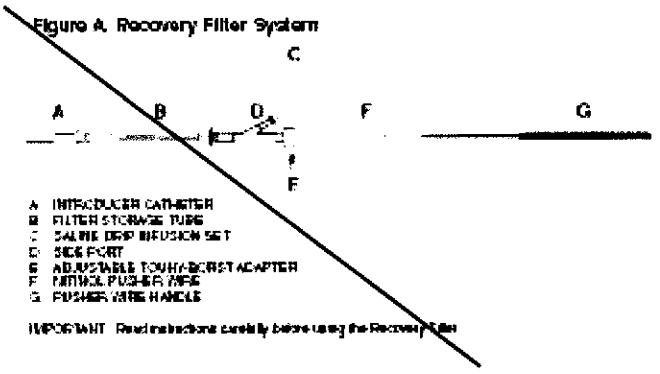
Deleted: excellent
Deleted: sheath
Deleted: prevents
Deleted: from
Deleted:
Deleted: Filter
Deleted: Delivery System.
Deleted:

lower level of filtration and the arms provide the upper level of filtration. The **Recovery** Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The **Recovery** Filter Delivery System is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the **Recovery** Filter, a storage tube with saline infusion port, and a pusher system. The **Recovery** Filter is packaged pre-loaded within the delivery storage tube.

Figure A. Recovery Filter System





C. Indications for Use

The **Recovery** Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- **Recovery** Filter may be removed according to the instructions supplied below under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

Caution: If the IVC diameter ~~corrected, inferior vena cava (IVC) diameter~~ exceeds 28 mm, the filter must not be inserted into the IVC.

The Recovery Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

Deleted: diameters up

Deleted: Delivery System

Deleted: sheath

Deleted: filter

Deleted: ·

Deleted: ·

Deleted: ·

Deleted: ·

Deleted: ·

Deleted: filter

Deleted: ·

Deleted: ·

Deleted: vena cava diameters greater

Deleted: ·

E. Warnings

Recovery Filter Implantation

1. The **Recovery** Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the **Recovery** Filter cannot be safely reloaded into the storage tube.
2. Do not deploy the filter unless IVC has been properly measured.
3. Delivery of the **Recovery** Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter.
4. The **Recovery** Filter System is designed for femoral approaches only. Never use the **Recovery** Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper **Recovery** Filter orientation within the IVC.
5. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.
6. Only use the **Recovery Cone®** Removal System to remove the **Recovery** Filter. Never re-deploy a removed filter.
7. Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.
8. Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
9. Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions spcified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.

See **Potential Complications** section for further information regarding other known filter complications.

Recovery Filter Removal

1. Do not attempt to remove the **Recovery** Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena caval wall.
2. Use only the Bard **Recovery Cone** Removal System (packaged separately) to retrieve the **Recovery** Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.

F. Precautions

Recovery Filter Implantation

1. The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age.[1]

Deleted: vena cava filter
Deleted: vena cava (
Deleted:)
Deleted: sheath
Deleted: -
Deleted: Filter
Deleted: Filter
Deleted: Filter
Deleted: sheath.
Deleted: 3
Deleted: inferior vena cava
Deleted: 4
Deleted: .
Deleted: .
Deleted: 5
Deleted: 6
Deleted: sheath
Deleted: Filter
Deleted: Filter

2. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
3. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
4. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
5. If misplacement or sub-optimal placement of the filter occurs, consider immediate retrieval. Retrieve the **Recovery** Filter using the **Recovery Cone** Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
6. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
7. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
8. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
9. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
10. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
11. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
12. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer catheter.

Recovery Filter Removal

1. Anatomical variances may complicate insertion and deployment of the **Recovery Cone** Removal System. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the **Recovery** Filter with the **Recovery Cone** Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.

Deleted: inferior vena cava

Deleted: ¶ ¶

Formatted: Font: Bold

Formatted: Font: Bold

Formatted: Font: Bold

Deleted: inferior vena cava

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent **pulmonary embolism**. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage.
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear.
- Stenosis at implant site.

All these above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One **Recovery** Filter and Delivery System that contains:
  - -One 48 cm, 7 French I.D. introducer catheter and dilator set
  - -One storage tube with pre-loaded **Recovery** Filter and pusher delivery system
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

Deleted: · Migration of the filter. This may be caused by placement in oversized vena cava diameters exceeding 28 mm or if proper anchoring techniques are not utilized. ¶

· Perforation of the vena cava wall. This may occur if proper insertion technique is not utilized.¶

· Caval occlusion. The probability of this occurring should be weighed against the inherent risk/benefit ratio for a patient who is experiencing

Deleted: , or who is likely to do so without intervention.

Deleted: ·

Deleted: sheath

Deleted: -

Formatted: Tabs: 0.25", Left

Deleted: -

Deleted: -

Deleted: -

Deleted: -

If the physician chooses to percutaneously remove the **Recovery** Filter, the **Recovery Cone** Removal System is available from C. R. Bard, Inc.

Deleted: - An entry kit consisting of a 0.038" 3 mm J-tipped guidewire, entry needle, #11 scalpel and 10-cc syringe is available from C. R. Bard,catalogue number 4000F.¶

Formatted: Font: Bold

Formatted: Font: Bold

I. Instructions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

NOTE: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

NOTE: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

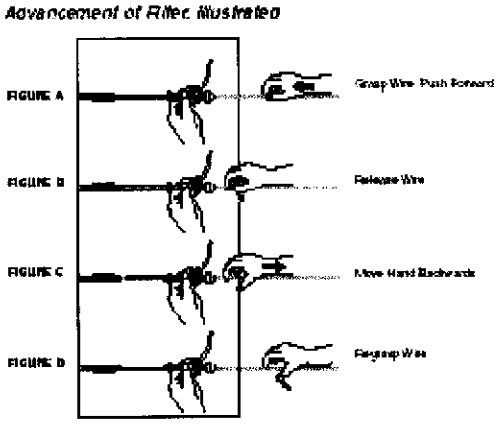
NOTE: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

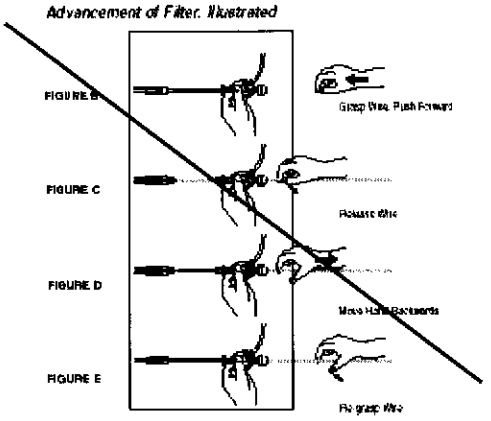
8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
10. Remove the filter and delivery system from Kit B.
11. Connect a 500-mL bag of saline to the sideport of the Y-adapter using a standard drip infusion set. Allow the saline infusion to flow around the filter in the storage tube for 5 seconds to soften it for passage through the introducer catheter. Adjust the infusion set to provide a rapid drip rate. Tighten the Touhy-Borst adapter

valve to minimize reflux of saline, but not so tight as to prevent the pusher wire from advancing freely.

NOTE: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

12. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein, allowing the saline infusion to flow into the IVC for a few seconds. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.





13. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.

Deleted: Filter
Deleted: Filter
Deleted: B-E)

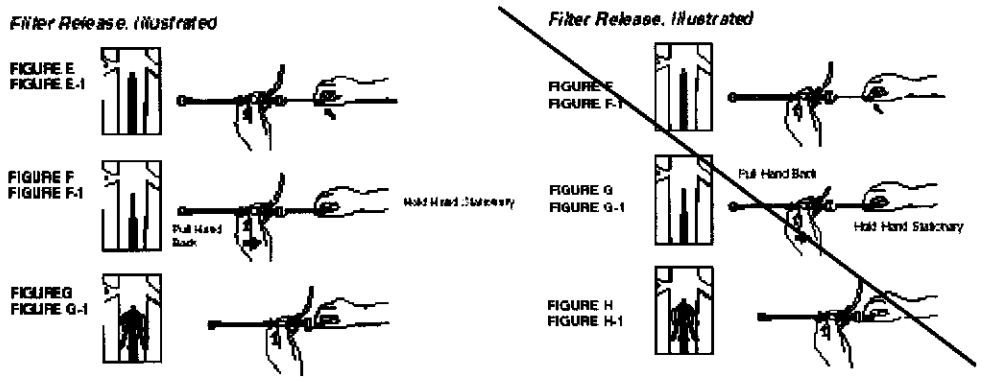
14. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

Deleted: Filter

Filter Release/Deployment

15. Deliver and release filter as described below:
    Figure E: Firmly hold the pusher wire handle.
    Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

Deleted: F
Deleted: F



NOTE: Do not deliver the filter by pushing it beyond the end of the introducer catheter. Instead, unsheath the stationary filter by withdrawing the introducer catheter as described below.

Position the filter tip 1 cm below the lowest renal vein.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter.

Figure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hands at the completion of the unsheathing process.

Figure G-1: The filter deployed in the IVC.

16. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire.
17. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

Caution: ~~It is strongly recommended that removal of the~~ Remove the Recovery Filter be done using the Recovery Cone only.

18. A follow-up venacavogram must be performed after withdrawing the introducer catheter into the iliac vein (typically 30 mL of contrast medium at 15 mL/s).
19. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Removal of Recovery Filter

Equipment Required

The following equipment is required for use:

- One **Recovery Cone** Removal System that contains:
  –One 75 cm, 10 French I.D. introducer catheter and dilator set
  –One Y-adapter with **Recovery Cone** and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer

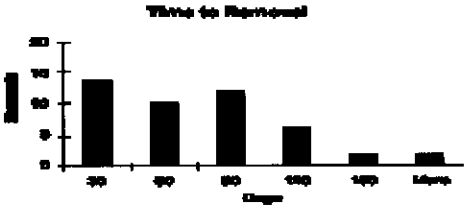
Deleted: Filter
Deleted: Filter
Deleted: ¶ ¶ ¶ ¶ ¶ ¶ <sp>Now release the Filter by unsheathing it in the IVC as follows:¶
Deleted: Filter
Deleted: G:
Deleted: G
Deleted: Filter
Deleted: H:
Deleted: H
Deleted: Filter
Deleted: delivery
Deleted: may
Deleted: <sp>¶
Formatted: Font: Bold
Deleted: delivery sheath
Formatted: Font: Bold

- 18 gauge entry needle
- 12 French dilator
- Saline
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience

The **Recovery** Filter has been used in Canada by a single investigator and two colleagues at six Toronto-area hospitals in 58 subjects, under the Special Access regulations. Although only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place from causes unrelated to filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, with an average of 60 days (see histogram below).



Follow-up post retrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein (n=1). One filter was removed surgically during a cancer operation where the mass was impinging on the filter. The two methods described in the Instructions for Use section were used to retrieve the filter in all but 4 cases, when a larger sheath was used, or a snare loop was attempted instead of using the Recovery Cone removal system. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.

Deleted:

Deleted: essentially

Deleted: of

Deleted: ¶
<sp>Follow-up post retrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein (n=1). One was removed surgically during a cancer operation where the mass was impinging on the filter. The two methods described in the Instructions for Use were used to retrieve the filter in all but 4 cases, when a larger sheath was used, or a snare loop was attempted instead of using the **Recovery** Cone Removal System. There was one case of asymptomatic pulmonary embolism when using the larger sheath.¶
The only other adverse event reported was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, minus the hook.¶
¶
¶
¶

Deleted: <sp>¶

Clinical Experience Summary Table	
Recovery Filters Implanted	58
Percutaneous Filter Removals	45
Surgical Filter Removals	1 (Concurrent to tumor resection)
Patient Age	8-89 years (52 years average)
Reason for Filter placement	
Contraindication to anticoagulation	40
Complications associated with anticoagulation	13
Failure of anticoagulation	3
Prophylaxis	2
Time to removal	1-161 days (60 days average)
Follow-up post-removal	1-901 days (325 average)
Filter Removal Complications	
Technical	0
Hook fracture secondary to stresses due to labor and birth and infrarenal placement	1
Asymptomatic pulmonary embolism post-removal	1

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the **Recovery Cone** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the **Recovery** Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the **Recovery** Filter.

Recovery Cone Insertion and Delivery

11. Remove the **Recovery Cone** and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone.

Formatted: Font: Bold
Deleted: of
Formatted: Font: Bold
Formatted: Font: Bold
Formatted: Font: Bold

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the Recovery Cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
15. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
16. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
17. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheath to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of Recovery Filter
Filter Removal, Illustrated

18. The capture of the **Recovery** Filter is illustrated in Figures A-E:
    Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.
    Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.
    Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.
    Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.
    Figure E: The filter has been retracted into the catheter.
19. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

20. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
21. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Deleted: easily
Deleted: removal cone
Deleted: wire
Deleted: e
Deleted: Cone
Formatted: Indent: Before: 0", Hanging: 0.5"
Formatted: Font: Bold
Formatted: Indent: Before: 0", Hanging: 0.5"
Deleted: 19.
Deleted: after
Deleted: 20.

Guidewire - Assisted Technique
Due to anatomical variances with respect to the position of the **Recovery** Filter, guidewire-assisted techniques may be used.
Use of a Guidewire
If it is difficult to align the cone with the Recovery Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.
Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip.
After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.
Advance the introducer catheter to slightly collapse the cone over the Filter tip.
Withdraw the guidewire into the pusher shaft.
Continue removing the Filter as described in step 18.
J. How Supplied
Each **Recovery** Filter is supplied preloaded in a storage tube. Each **Recovery** Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.
Note: After use, the Recovery Filter Delivery System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
The **Recovery** Filter should be stored in a cool (room temperature), dry place.

K. Warranty
Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.
TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.
Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.
Labeling Issue Date: 10/04
In the event 3 years have elapsed between this date and product use, the user should contact C. R. Bard, Inc. to see if additional product information is available.

Deleted:
Deleted: advance
Deleted: over
Formatted: Font: Not Bold
Deleted: Filter
Deleted: sheath
Deleted: Filter
Deleted: Filter
Deleted: Filter
Deleted: Filter
Deleted: Filter
Deleted: sheath
Deleted: its
Deleted: to be used
Deleted: a
Formatted: Font: Bold
Formatted: Font: Bold
Formatted: Font: Bold
Formatted: Font: Bold
Deleted: and insertion supplies
Formatted: Font: Bold
Formatted: Font: Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Deleted:
Deleted: 12/03

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism, Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.

Bard Peripheral Vascular, Inc.
P.O. Box 1740
Tempe, AZ 85280-1740
USA

TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-966-7062
1-800-440-5376
www.bardpv.com

CE 0086 EEA Authorized Representative Bard Limited Crawley UK RH11 9BP

Deleted: 2003,

Formatted: Font: Bold

Deleted: ACR Standard For The Performance Of

Deleted: (IVC)

Deleted: For The

Deleted: Of

Deleted: - 2000 (Res.12), Effective 01/01/01

Formatted: Indent: Before: 0", First line: 0"

Formatted: Font: Bold

Deleted: <sp>

Formatted: Indent: Before: 0", First line: 0"

DRAFT CUSTOMER COMMUNICATION

IMPORTANT: INFORMATION FOR USE UPDATE

DEAR DOCTOR:

Attached is the latest version of the Information for Use (IFU) for the Recovery® Filter System from Bard Peripheral Vascular, Inc. Please take time to read this document in its entirety.

After 20 months of product availability, we have gained valuable clinical information about the usage of our product. In addition, we have reviewed the current literature, compared our labeling to that in use for other IVC filters, and consulted with experts in the field of thromboembolic disease treatment and prevention (interventional radiology, hematology, general internal medicine, vascular medicine, and the following surgical disciplines: vascular, trauma, and general surgery). Based on this information, we have revised the Recovery Filter System IFU to reflect what we believe are best practices and to highlight important warnings and precautions.

Following are key points from our revised IFU. In brief, we wish to reemphasize the following patient selection, procedure and device information:

- **Under Warnings**: The following information has been added:
  - Do not deploy the filter unless IVC has been properly measured.
  - Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in cardiopulmonary symptoms some of which have led to retrieval of the filter fragment through open-heart surgery or other invasive procedures. Most cases of filter fracture, both those reported through adverse event reporting and in the published literature, have been reported without clinical consequence.
  - Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs has been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.

- **Under Precautions**: The following information has been added:
  - Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
  - When measuring caval dimensions, consider an angiographic catheter or Intravascular Ultrasound (IVUS) if there is any question about caval morphology.
  - If misplacement or sub-optimal placement of the filter occurs, consider immediate retrieval. Retrieve the ***Recovery*** Filter using the ***Recovery Cone*** Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
  - In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
  - If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
  - The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
  - The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
  - It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.

- Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer catheter.

- **Under Potential complications**: After reviewing other IVC manufacturer IFUs, the following information was rewritten as follows:

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure. Possible complications include, but are not limited to, the following:

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs has been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in cardiopulmonary symptoms some of which have led to retrieval of the filter fragment through open-heart surgery or other invasive procedures. Most cases of filter fracture, both those reported through adverse event reporting and in the published literature, have been reported without clinical consequence.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage.
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear.
- Stenosis at implant site.

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

We hope this information is helpful to you and your patients in using the Recovery Filter System. Should you have any questions on the enclosed Instructions for Use, please contact your Territory Manager or our Medical Services and Support department at 1-800-562-0027.

Regards,

Janet Hudnall
Marketing Manager
Vena Cava Filters

COMPLICATION/TRACKABLE EVENT COMPARISON CHART

Potential Complication	Recovery Filter Total No. of Events thru 9/30/04	Recovery Filter Rate based on Sales	Complication/ Trackable Event Rates from Society of Interventional Radiology (all filters)*	Threshold % from Society of Interventional Radiology (all filters)**	Comments
Movement/Migration (2cm +)***	20	0.117%	0-18%	2%	
Filter Fracture	26	0.152%	2-10%	Not reported	
Perforation	11	0.064%	0-41 %	Not reported	
Pulmonary Embolism	2	0.012%	0.5-6%	5%	
Caval Thrombosis/occlusion	0	0	2-30%	10%	
Extravasation of Contrast at time of cavagram	1	0.006%	Not reported	Not reported	
Air Embolism	0	0	Not reported	Not reported	
Hematoma or nerve injury at puncture or retrieval site	0	0	0-6%	1%	
Hemorrhage	0	0	5-50%	Not reported	Listed as insertion problems
Restriction of blood flow	0	0	1-15%	Not reported	Listed as other complications
Occlusion of small vessels	0	0	1-15%	Not reported	Listed as other complications
Distal Embolization	0	0	2-5%	2%	
Infection	0	0	1-15%	Not reported	Listed as other complications
Intimal Tear	0	0	5-50%	Not reported	Listed as insertion problems
Stenosis at implant site	0	0	3-10%	Not reported	Listed as other complications
Death (includes all events listed above)	8	0.047%	0.12%	<1%	

*Grassi CJ, Swan TL, Cardella JF, et al. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. J Vasc Interv Radiol 2003; 14:S271-S275.

** Suggested Thresholds for individual practices for purposes of case review

***Migration/Movement includes filter embolization as described in Grassi, above.

QUALITY IMPROVEMENT ARTICLE

Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism

Clement J. Grassi, MD, Timothy L. Swan, MD, John F. Cardella, MD, Steven G. Meranze, MD, Steven B. Oglevie, MD, Reed A. Omary, MD, Anne C. Roberts, MD, David Sacks, MD, Mark I. Silverstein, MD, Richard B. Towbin, MD, and Curtis A. Lewis, MD, MBA, for the Society of Interventional Radiology Standards of Practice Committee

J Vasc Interv Radiol 2003; 14:S271–S275

Abbreviations: IVC = inferior vena cava, PE = pulmonary embolism

PULMONARY embolism (PE) continues to be a major cause of morbidity and mortality in the United States. Estimates of the incidence of nonfatal PE range from 400,000 to 630,000 cases per year, and 50,000 to 200,000 fatalities per year are directly attributable to PE (1–4). The current preferred treatment for deep venous thrombosis and PE is anticoagulation therapy. However, as many as 20% of these patients will have recurrent PE (1,5,6).

Interruption of the inferior vena cava (IVC) for the prevention of PE was first performed in 1893 with use of surgical ligation (7). Over the years, surgical interruption took many forms (ligation, plication, clipping, or stapling) but IVC thrombosis was a frequent complication after these procedures. Endovascular approaches to IVC interruption became a reality in 1967 after the introduction of the Mobin-Uddin filter (8).

Many devices have since been developed for endoluminal caval interruption but, currently, there are six devices commercially available in the United States. These devices are designed for permanent placement. For detailed information regarding each of these filters, the reader is referred to several published reviews (9–12). Selection of a device requires knowledge of the clinical settings in which filters are used, evaluation of the clot trapping efficiency of the device, occlusion rate of the IVC and access vein, risk of filter migration, filter embolization, structural integrity of the device, and ease of placement.

Percutaneous caval interruption can be performed as an outpatient or inpatient procedure. However, practically speaking, most filter placements will occur in the inpatient population because of ongoing medical therapy for acute thromboembolic disease or underlying illness.

The IVC should be assessed with imaging before placement of a filter, and the current preferred imaging method is vena cavography. Before filter selection and placement, the infrarenal IVC length and diameter should be measured, the location and number of renal veins determined, IVC anomalies (eg, duplication) defined, and intrinsic IVC disease such as preexisting thrombus or extrinsic compression excluded. The ideal placement for the prevention of lower extremity and pelvic venous thromboembolism is the infrarenal IVC. The apex or superior aspect of any filtration device should be at or immediately inferior to the level of the renal veins according to the manufacturers' recommendations. In specific clinical circumstances, other target locations may be appropriate.

Percutaneous caval interruption is commonly accomplished through right femoral and right internal jugular vein approaches; however, other peripheral and central venous access sites can be used. Filters can be placed in veins other than the vena cava to prevent thromboembolism. Implant sites have included iliac veins, subclavian veins, superior vena cava, and IVC (suprarenal and infrarenal). This document will provide quality improvement guidelines for filter placement within the inferior vena cava because of the limited data available for implantation sites other than the IVC. The patient's clinical condition, the type of filter available, the alternative access sites available, and the expertise of the treating physician should always be considered when the decision to place an IVC filter has been made.

These guidelines are written to be used in quality improvement programs to assess percutaneous interruption of the IVC to prevent pulmonary embolism. The most important processes of care are (*a*) patient selec-

This article first appeared in J Vasc Interv Radiol 2001; 12:137–141.

A complete list of the members of the SIR Standards of Practice Committee is given at the end of this article. Address correspondence to SIR, 10201 Lee Hwy, Suite 500, Fairfax, VA 22030.

DOI: 10.1097/01.RVI.0000094597.83406.50

tion, (*b*) performing the procedure, and (*c*) patient monitoring. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

DEFINITIONS

Procedural Success: Deployment of a filter such that the filter is judged suitable for mechanical protection against PE.

Procedural Failure: The procedure concludes with unsatisfactory filter deployment such that the patient has inadequate mechanical protection against PE.

Death: Procedurally related death directly attributable to the filter itself documented by clinical findings, imaging, or autopsy.

Recurrent PE: Pulmonary embolism occurring after filter placement documented by pulmonary arteriography, cross sectional imaging, altered ventilation-perfusion lung scan to high probability of PE, or autopsy.

IVC Occlusion: Presence of an occluding thrombus in the IVC occurring after filter insertion and documented by US, CT, MR imaging, venography, or autopsy.

IVC Penetration: Penetration of the vein wall by filter hooks with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration is filter strut or anchor devices extending more than 3 mm outside the wall of the IVC demonstrated by CT, US, venography, or autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (see below).

Filter Embolization: Post-deployment movement of the filter to a distant anatomic site completely out of the target zone.

Migration: Filter migration defined as a change in filter position compared to its deployed position (either cranial or caudal) more than 2 cm as documented by plain film imaging, CT, or venography.

Filter Fracture: Any loss of structural integrity (ie, breakage or separation) of the filter documented by imaging or autopsy.

Insertion Problems: Filter or deployment system related malfunctions such as incomplete filter opening, filter tilt more than 15° from the IVC axis (eg, non–self-centering filters), misplacement of filter outside of the infrarenal IVC when the operators' intent is to place the filter in the infrarenal IVC (eg, when a portion of the filter is within one iliac vein), or prolapse of filter components. Filter malposition requiring surgical removal is considered an insertion problem complication.

Access Site Thrombus: Occlusive or nonocclusive thrombus developing after filter insertion at the venotomy site (13–17).

Other access site complications with clinical sequelae: Arteriovenous fistula, hematoma, or bleeding requiring a transfusion, hospitalization (either admission or extended stay), or further treatment for management.

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold a review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in: admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix 1). The complication rates and thresholds listed herein refer to *major* complications.

INDICATIONS

Accepted

1. Patients with evidence of pulmonary embolus or IVC, iliac, or femoral-popliteal deep venous thrombosis and one or more of the following (13–16):
   a. Contraindication to anticoagulation
   b. Complication of anticoagulation
   c. Failure of anticoagulation
      i. Recurrent PE despite adequate therapy
      ii. Inability to achieve adequate anticoagulation
2. Massive pulmonary embolism with residual deep venous thrombus in a patient at risk for further PE
3. Free-floating iliofemoral or IVC thrombus
4. Severe cardiopulmonary disease and deep venous thrombosis (eg, cor pulmonale with pulmonary hypertension)
5. Poor compliance with anticoagulant medications

Additional Indications for Selected Patients

1. Severe trauma without documented PE or deep venous thrombosis
   a. Closed head injury
   b. Spinal cord injury
   c. Multiple long bone or pelvic fractures
2. High-risk patients (eg, immobilized, intensive care patients, prophylactic preoperative placement in patients with multiple risk factors for venous thromboembolism)

Suprarenal Filter Placement

1. Renal vein thrombosis
2. IVC thrombosis extending above the renal veins
3. Filter placement during pregnancy; suprarenal placement is also appropriate in women of childbearing age
4. Thrombus extending above previously placed infrarenal filter

Table 1
Complications

Complications	Reported Rates (%)	Threshold (%)
Death (7)	0.12	<1
Recurrent PE (17–22)	0.5–6	5
IVC Occlusion (11,17,19,20,23–27)	2–30	10
Filter Embolization (17,24,28–37)	2–5	2
Access Site Thrombosis—Major (see Appendix 1) (38,39)	0–6*	1

* Includes reported rates of both major and minor complications.

Table 2
Other Trackable Events

Other Trackable Events	Reported Rates (%)
IVC Penetration (7,17,19,23,27,40,52)*	0–41
Migration (7,9,10,17,19–21,26,41,42)*	0–18
Filter Fracture (17,24)	2–10
Access Site Thrombus	
All types (7,38,43,44)	0–25
Occlusive (38,45)	3–10
Insertion Problems (7,17,19–22,24,26,41,43,46,47)	5–50
Other complications (48,49)	1–15

Note.—The rate of clinically significant penetration is undefined in the literature (39,50,52).
* Clinically significant penetration and migration are believed to be rare.

5. Pulmonary embolism after gonadal vein thrombosis
6. Anatomic variants: duplicated IVC, low insertion of renal veins

RELATIVE CONTRAINDICATIONS (TO PERCUTANEOUS PLACEMENT)

1. Uncorrectable severe coagulopathy (eg, patients with liver or multisystem failure).
2. Caution should be exercised when placing a filter in patients with bacteremia or untreated infection; clinical judgement should be applied in these situations weighing the theoretical risk of implant infection versus the risk of PE.

For pediatric and young adult patients, filter placement indications should be strict because the long-term effects and durability of the devices are not precisely known.

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the department will review the process of patient selection.

SUCCESS

It is expected that the technical success for percutaneously placed IVC filters will be 97% or better in experienced hands. Therefore, the proposed threshold for review of technical failures should be 3%.

COMPLICATIONS

Each currently available filter has been studied extensively as part of the Food and Drug Administration approval process. Few comparative studies have been completed evaluating all filters in one project, and those that have done so have been retrospective analyses. Complication rates are highly variable depending on the filter being studied. For simplicity, these guidelines will not suggest threshold rates for each individual filter; rather, filtration devices will be considered as a group (**Table 1**).

Published rates for individual types of complications are highly dependent on patient selection and are, in some cases, based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to exceed a complication-specific threshold when the complication occurs in a small volume of patients, for example, early in a quality improvement program (18–52).

OTHER TRACKABLE EVENTS

Because an IVC filter is a permanent implantable device and because this device is sometimes placed in relatively young patients, several other trackable parameters when observed are appropriate to record in a quality improvement program. The events listed in **Table 2** may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

Acknowledgments: Clement Grassi, MD, and Timothy Swan, MD, authored the first draft of this document and served as topic leaders during the subsequent revisions of the draft. Dr. John Cardella is chair of the SIR Standards of Practice Committee. Curtis Lewis, MD, MBA, is Councilor of the SIR Standards Division. All other authors are listed alphabetically. Other members of the Standards of Practice Committee and SIR who participated in the development of this clinical practice guideline are John E. Aruny, MD, Curtis Bakal, MD, MPH, Dana Burke, MD, Paramjit Chopra, MD, Steven J. Citron, MD, Patricia E. Cole, PhD, MD, Martin Crain, MD, Andrew Davis, MD, Alain Drooz, MD, Elizabeth Drucker, MD, JD, Neil Freeman, MD, Jeff Georgia, MD, Richard Shlansky-Goldberg, MD, Richard Gray, MD, Sue Hanks, MD, Ziv Haskal, MD, James Husted, MD, Michael Todd Jones, MD, Patrick C. Malloy, MD, Louis Martin, MD, Timothy C. McCowan, MD, Theodore Mirra, MD, Sally Mitchell, A. Van Moore, MD, Calvin D. Neithamer, MD, Nilesh Patel, MD, Paravati Ramchandani, MD, Kenneth S. Rholl, MD, Orestes

Sanchez, MD, Harjit Singh, MD, Bob Smouse, MD, Patricia Thorpe, MD, Scott Trerotola, MD, Anthony Venbrux, MD, and Daniel Wunder, MD.

APPENDIX 1: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. Result in no therapy, no consequence, or

B. Result in nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (<48 hours),

D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours),

E. Cause permanent adverse sequelae, or

F. Cause death

APPENDIX 2: METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from standards of practice committee member practices and, when available, the SIR HI-IQ® system National Database. Consensus on statements in this document was obtained with use of a modified Delphi technique (53,54).

Technical documents specifying the exact consensus and literature review methodologies are available upon request from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

References

1. Dalen F, Albert JS. Natural history of pulmonary emboli. Prog Cardiovas Dis 1975; 17:259–270.
2. Consensus Development Panel. Prevention of venous thrombosis and pulmonary embolism. JAMA 1986; 256: 744–749.
3. Goldhaber SZ, Hennekens CH, Evans DA, et al. Factors associated with correct antemortem diagnosis of major pulmonary embolus. Am J Med 1982; 73:822–826.
4. Clagett GP. Basic data related to venous thromboembolism. Ann Vasc Surg 1988; 2:402–405.
5. Silver D, Sabiston DC. The role of vena cava interruption in management of pulmonary embolism. Surgery 1975; 77:1–10.
6. Glenny RW. Pulmonay embolism. South Med J 1987; 80:1266–1276.
7. Becker DM, Philbrick JT, Selby JB. Inferior vena cava filters: indication, safety, effectiveness. Arch Intern Med 1992; 152:1985–1994.
8. Mobin-Uddin K, Smith PE, Martinez LO, Lombardo CR, Jude JR. A vena caval filter for the prevention of pulmonary embolus. Surg Forum 1967; 18: 209–211.
9. Grassi CJ. Inferior vena caval filters: analysis of five currently available devices. AJR Am J Roentgenol 1991; 156: 813–821.
10. Dorfman GS. Percutaneous inferior vena caval filters. Radiology 1990; 174: 987–992.
11. Greenfield LJ, DeLucia A III. Endovascular therapy of venous thromboembolic disease. Surg Clin North Am 1992; 72:969–989.
12. Savader SJ. Inferior vena cava filters. In: Savader SJ, Trerotola S, eds. Venous interventional radiology with clinical perspectives. New York, NY: Thieme, 1996; 367–399.
13. Ray CE, Kaufman JA. Complications of inferior vena cava filters. Abdom Imaging 1996; 21:368–374.
14. Kaufman JA, Geller SG. Indications for vena cava filters. AJR Am J Roentgenol 1995; 164:256–257.
15. Valji K. Vascular and interventional radiology. Philadelphia, Pa: Saunders, 1999; 305.
16. Norris C, Greenfield L, Hermanson J. Free-floating iliofemoral thrombus: a risk of pulmonary embolism. Arch Surg 1985; 120:806–808.
17. Ferris EJ, McCowan TC, Carver DK, McFarland DR. Percutaneous inferior vena caval filters: follow-up of seven designs in 320 patients. Radiology 1993; 188:851–856.
18. Greenfield LJ, Proctor MC. Twenty-year clinical experience with the Greenfield filter. Cardiovasc Surg 1995; 3:199–205.
19. Millward SF, Peterson RA, Moher D, et al. LGM (Vena-Tech) vena caval filter: experience at a single institution. J Vasc Interv Radiol 1994; 5:351–356.
20. Crochet DP, Stora O, Ferry D, et al. Vena Tech-LGM filter: long term results of a prospective study. Radiology 1993; 188:857–860.
21. Simon M, Athanasoulis CA, Kim D, et al. Simon nitinol inferior vena cava filter: initial clinical experience. Radiology 1989; 172:99–103.
22. Greenfield L, Cho KJ, Proctor M, et al. Results of a multicenter study of the modified hook-titanium Greenfield filter. J Vasc Surg 1991; 14:253–257.
23. Magnant JG, Walsh DB, Juravsky LI, Cronenwett JL. Current use of inferior vena cava filters. J Vasc Surg 1992; 16:701–706.
24. McCowan TC, Ferris EJ, Carver DK, Molpus WM. Complications of the nitinol vena cava filter. J Vasc Interv Radiol 1992; 3:401–408.
25. Hye RJ, Mitchell AT, Dory CE, Freischlag JA, Roberts AC. Analysis of the transition to percutaneous placement of Greenfield filters. Arch Surg 1990; 125:1550–1553.
26. Ricco JF, Crochet D, Sebilotte P, et al. Percutaneous transvenous caval interruption with "LGM" filter: early results of a multicenter trail. Ann Vasc Surg 1988; 3:242–247.
27. Lang W, Schweiger J, Hofmann-Preiss K. Results of long-term venacavography study after placement of a Greenfield vena caval filter. J Cardiovasc Surg 1992; 33:573–578.
28. Atkins CW, Thurer RL, Waltman AC, Margolies MN, Schneider RC. A misplaced caval filter: its removal from the heart without cardiopulmonary bypass. Arch Surg 1980; 115:1133–1135.
29. Casteneda F, Herrera M, Cragg AH, et al. Migration of a Kimray Greenfield filter to the right ventricle. Radiology 1983; 149:690–691.
30. Friedell ML, Goldenkranz RJ, Parsonnet V, et al. Migration of a Greenfield filter to the pulmonary artery: a case report. J Vasc Surg 1986; 3:929–931.
31. Urbaneja A, Fontaine AB, Bruckner M, Spigos DG. Evulsion of a vena tech filter during insertion of a central venous catheter. J Vasc Interv Radiol 1994; 5:783–785.
32. Loesberg A, Taylor FC, Awh MH. Dislodgment of inferior vena caval filters during blind insertion of central venous catheters. AJR Am J Roentgenol 1993; 161:637–638.
33. Puram B, Maley TJ, White NM, Rotman HH, Miller G. Acute myocardial infarction from the migration of a Greenfield filter. Chest 1990; 98:1510–1511.
34. Bach JR, Zaneuski R, Lee H. Cardiac arrhythmias from malpositioned Greenfield filter in a traumatic quadriplegic. Am J Phys Med Rehabil 1990; 69:251–253.
35. Villard J, Detry L, Clermont A, Pinet F. Eight cases of Greenfield filters in the right heart cavities: their surgical treatment. Ann Radiol 1987; 30:102–104.
36. LaPlante JS, Contractor FM, Kiproff PM, Khoury MB. Migration of the Si-

mon nitinol vena cava filter to the chest. AJR Am J Roentgenol 1993; 160: 385–386.
37. Poillaud C, Ollitraut J, Paillard F, Biron Y, Gouffault J. Proximal migration of a caval filter: apropos of a case. Ann Cardiol Angeiol (Paris) 1988; 37:129–13140.
38. Molgaard CP, Yucel EK, Geller SC, Knox TA, Waltman AC. Access-site thrombosis after placement of inferior vena cava filters with 12–14 F delivery sheaths. Radiology 1992; 185:257–261.
39. Blebea J, Wilson R, Waybill P, et al. Deep venous thrombosis after percutaneous insertion of vena caval filters. J Vasc Surg 1999; 30:821–829.
40. Athanasoulis CA. Complications of vena cava filters. Radiology 1993; 188: 614–615.
41. Murphy TP, Dorfman GS, Yedlicka JW, et al. LGM vena cava filter: objective evaluation of early results. J Vasc Interv Radiol 1991; 2:107–115.
42. Vesely TM. Technical problems and complications associated with inferior vena cava filters. Sem Intervent Radiol 1994; 11:121–133.
43. Sweeney TJ, Van Aman ME. Deployment problems with the titanium Greenfield filter. J Vasc Interv Radiol 1993; 4:691–694.
44. Millward SF, Marsh JI, Peterson RA, et al. LGM (Vena Tech) vena cava filter: clinical experience in 64 patients. J Vasc Interv Radiol 1991; 2:429–433.
45. Hicks ME, Middleton WD, Picus D, Darcy MD, Kleinhoffer MA. Prevalence of local venous thrombosis after transfemoral placement of a Bird's Nest vena caval filter. J Vasc Interv Radiol 1990; 1:63–68.
46. Moore BS, Valji K, Roberts AC, et al. Transcatheter manipulation of asymmetrically opened titanium Greenfield filters. J Vasc Interv Radiol 1993; 4:687–690.
47. Teitelbaum GP, Jones DL, van Breda A, et al. Vena caval filter splaying: potential complication of use of the titanium Greenfield filter. Radiology 1989; 173:809–814.
48. Grassi CJ, Bettmann MA, Rogoff P, Reagan K, Harrington DP. Femoral arteriovenous fistula after placement of a Kimray-Greenfield filter. AJR Am J Roentgenol 1988; 151:681–682.
49. Iuanow E, Kandarpa K, Chopra R, Grassi CJ. Bleeding complications in patients undergoing percutaneous vena cava filter placement using new low profile introduction systems. Presentation at: American Roentgen Ray Annual Meeting, April 1993, San Francisco, Calif; 27.
50. Appleberg M, Crozier JA. Duodenal penetration by a Greenfield caval filter. Aust N Z J Surg 1991; 61:957–960.
51. Howerton RM, Watkins M, Feldman L. Late arterial hemorrhage secondary to a Greenfield filter requiring operative intervention. Surgery 1991; 109:265–268.
52. Simon M. Vena cava filters: prevalent misconceptions. J Vasc Interv Radiol 1999; 10:1021–1024.
53. Fink A, Kosecoff J, Chassin M, Brook RH. Consensus methods: characteristics and guidelines for use. Am J Public Health 1984; 74:979–983.
54. Leape LL, Hilborne LH, Park RE, et al. The appropriateness of use of coronary artery bypass graft surgery in New York State. JAMA 1993; 269:753–760.

The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

EXHIBIT G

Contains Nonbinding Recommendations

Draft – Not for Implementation

Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals")

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on December 31, 2015.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the Office of Communication and Education, 301-796-5660 or the Office of Surveillance and Biometrics, 301-796-6006.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Communication and Education
Office of Surveillance and Biometrics

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1500027 to identify the guidance you are requesting.

Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals")

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) is issuing this draft guidance to describe the Agency's policy for notifying the public about medical device "emerging signals." For the purposes of this guidance, an emerging signal is new information about a medical device used in clinical practice: 1) that the Agency is monitoring or analyzing, 2) that has the potential to impact patient management decisions and/or alter the known benefit-risk profile of the device, 3) that has not yet been fully validated or confirmed, and 4) for which the Agency does not yet have specific recommendations.

At the time a medical device is approved or cleared, it has a benefit-risk profile that health care providers, patients, and consumers use to make treatment decisions. Once a medical device is on the market, new information, including unanticipated problems, may change the benefit-risk profile of a device. Timely communication of emerging signals may help health care providers, patients, and consumers make informed treatment choices based on the most current available information. This draft guidance document proposes criteria, timeframes, a method of communication, and follow-up for FDA communications for emerging signals. This document does NOT address findings of postmarket safety or reduced benefit that are confirmed, or for which the Agency has specific recommendations for consumers, patients, health care providers, health care facilities, or industry.

Historically, the FDA has communicated important medical device postmarket information after having completed an analysis of available data and, in most cases, after having reached a

decision about relevant recommendations for the device user community and about whether further regulatory action is warranted. For such safety or effectiveness issues, FDA generally will provide new or amended advice or instructions for patients, practitioners, and/or consumers regarding the safe and effective use of the device, based on the new data. In these cases, the Agency uses a variety of mechanisms to communicate publicly, including recall notices, safety communications, and press releases.

However, in addition to these types of public communications, we believe there also is a need to notify the public about emerging signals that the Agency is monitoring or analyzing, even when the information has not been fully analyzed, validated or confirmed, and for which the Agency does not yet have specific recommendations.

Because of the evolving nature of this information, FDA would be sharing it with the public at an early stage of the Agency's assessment and evaluation of the signal. Further, in contrast to a device safety communication, a communication regarding an emerging signal may lack certainty about the significance of the information, including whether it represents a new, potentially causal association, or a new aspect of a known association (e.g., increased rate or severity of event), between a medical device and one or more adverse events or outcomes.

Timely communication about emerging signals is intended to provide health care providers, patients, and consumers with access to the most current information concerning the potential benefits and risks of marketed medical devices so that they can make informed treatment choices based on all available information. Such communication may also reduce or limit the number of patients exposed to the potential risk while the issue is being further evaluated. In addition, communicating emerging signals may also promote enhanced vigilance on the part of clinicians, risk managers, patients and consumers, who may respond by increasing their reporting to FDA. This may in turn assist the Agency in further understanding the emerging signal.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

All medical devices have benefits and risks. Health care providers, patients, and consumers must weigh these benefits and risks when making health care decisions. FDA weighs probable benefit to health from the use of the device against any probable risk of injury or illness from such use in determining the safety and effectiveness of a device.[1] However, not all information regarding benefits and risks for a given device may be fully known or characterized prior to the device reaching the market. New information about the safety and/or effectiveness of the device often

[1] *See* 21 U.S.C. 360c(a)(2) and 21 C.F.R. 860.7.

becomes available once the device is more widely distributed and used under real-world conditions of actual clinical practice.

The FDA strives to provide current information concerning the potential benefits and risks of marketed medical devices to health care providers, patients, and consumers so that they can make informed treatment choices based on all available information.[2] We also recognize the potential unintended consequences of public communication about emerging signals, prior to confirmation and full evaluation of the data, including the possibility that a beneficial device's use may be avoided or inappropriately stopped because of uncertain or unproven risks or uncertainty around the benefits. This latter concern is particularly relevant when the Agency has not yet developed specific recommendations. However, FDA believes that when an emerging signal meets the criteria described in Section III, including that it is based on reliable data, the benefits of providing early information to the public outweigh these risks if communicated carefully and thoughtfully.

Emerging signals may include, but are not limited to, a newly recognized type of adverse event associated with a medical device, an increase in the severity or frequency of reporting of a known event, new product-product interactions, device malfunctions or patient injuries potentially related to improper device use or design, or a reduction in benefit to the patient. A medical device emerging signal may be associated with one product from one manufacturer, one type of product or similar products from multiple manufacturers, or multiple different product types from multiple different manufacturers (e.g., materials issues).

The gathering and interpretation of the additional data needed to fully characterize an emerging signal can be complex, and it may take weeks or months to conduct the analyses to understand the implications of the signal for device performance and for its clinical significance. In addition, in certain circumstances, the FDA may collaborate with other federal and state public health agencies, or elect to seek recommendations from one of its Advisory Committees to assist in evaluating available information pertaining to a signal. These factors contribute to variability in the amount of time needed to sufficiently evaluate an emerging signal and to determine whether public communication of specific recommendations and/or regulatory action are warranted.

III. Considerations for Determining When FDA Will Issue a Public Notification About an Emerging Signal

FDA considers many factors in the course of evaluating and communicating about medical device emerging signals. These factors may include, but are not limited to, the following:

- Seriousness of the adverse event(s) (e.g., severity and reversibility) relative to the known benefits of the device;

[2] FDA discloses such information pursuant to all applicable laws, regulations, and policies, including sections 301(j) and 520(c) of the Federal Food, Drug, and Cosmetic Act, the Trade Secrets Act, the Privacy Act, and FDA disclosure regulations.

- Magnitude of the risk (e.g., likelihood of occurrence);
- Magnitude of the benefit;
- Strength of the evidence of a causal relationship between the use of a device and the adverse event;
- Extent of patient exposure (e.g., how broadly is the device used, is the device still actively manufactured and distributed);
- Whether there is a disproportionate impact on vulnerable patient populations (e.g., children, pregnant women, elderly, cancer patients, chronically ill, at-home/unmonitored);
- Potential for preventing, identifying, monitoring or mitigating the risk;
- Availability of alternative therapies;
- Implications for similar or related devices (e.g., multiple models from multiple manufacturers);
- Anticipated time for completion of initial FDA assessment and development of recommendations;
- Accuracy and availability of information already in the public domain.

At times, the decision to communicate about a medical device emerging signal may be affected by information the public has received from sources other than FDA, such as in the mainstream or social media. In some cases, the safety of a particular medical device or type of device may be publicly questioned based on incorrect, incomplete, or misleading information. In such cases, FDA may issue a statement or engage in other methods of communication to clarify or correct information and respond to public interest.

The decision to provide public information about a medical device emerging signal is intended to give health care providers, patients and consumers access to the most current information about an emerging signal. It does not mean that FDA has concluded that there is a causal relationship between the medical device and the emerging signal. Nor does communicating about the emerging signal mean that FDA is advising health care providers, patients, or consumers to limit their use of the device.

Whenever FDA discusses medical device safety, it should exercise judgment in determining whether and when to communicate and what to say. FDA staff should strongly consider public communication about an emerging signal when all of the following statements apply:

1. the information represents a new, potentially causal association, or a new aspect of a known association (e.g., increased rate or severity of event or reduced benefit), between a medical device and one or more adverse events or clinical outcomes;
2. the available information is reliable and supported by sufficient strength of evidence; and
3. the information could have important clinical implications for patient management decisions and/or could it significantly alter the known benefit-risk profile of the device.

FDA staff should conduct an initial assessment of the need to communicate about an emerging signal within 30 days of receiving the information.

If during the evaluation of a signal, a decision is made to NOT communicate, FDA staff should conduct an internal reassessment of the decision within 30 days of receiving new information, using the considerations described above.

IV. Content of Communication and Follow-up

FDA strives to keep all communications clear and understandable. We consider elements of human behavior in our decision to communicate and in the content of our communication. We realize that risk information provided without context may alarm patients, causing them to discontinue therapy with a beneficial device or to avoid a potentially beneficial therapy. In our communications on medical device emerging signals, whenever possible and appropriate, we will include specific information on the known benefits and risks of the device and its use, as well as information on the emerging signal.

To provide consistency, FDA proposes to communicate medical device emerging signals using the format and content described in Appendix A of this guidance. Once a medical device emerging signal is communicated, the Agency may provide updates that:

- Provide new information related to the emerging signal collected since the initial public notification;
- Update the public that no additional substantive information is available and/or that no known change in the benefit-risk profile of the device has occurred since the last posting;
- Notify the public of additional actions being taken or completed by FDA and/or the manufacturer(s).

Updates to the communication should be posted to the FDA website at least twice per year, or more often as necessary and appropriate, until either the Agency issues a more formal "Safety Communication" containing specific recommendations for patients, health care providers, and/or health care facilities, or until the signal evaluation is otherwise completed and the public is notified of the Agency's conclusions.

Appendix A: Format of Public Notification about a Medical Device Emerging Signal

Early Communication: FDA Evaluating [summary of issue]

This communication reflects FDA's current assessment of available information about [issue]. It is intended to highlight this information at an early stage in the FDA's review, before the FDA has completed a full investigation or determined whether this information warrants regulatory action. Posting this information does not mean that FDA has concluded there is a causal relationship between the medical device and the emerging signal. Nor does it mean that the FDA is advising patients or health care professionals to discontinue or modify use of these products. The FDA will update this document when additional information or analyses become available.

Date:
Device (including known benefits and risks):
Summary of Emerging Signal:
Additional Information for Patients and Health Care Professionals (if any):
Ongoing FDA Actions:
How to Report Problems to the FDA:

EXHIBIT H

United States District Court

District of Nevada

Notice of Electronic Filing

The following transaction was entered on 2/2/2015 at 1:22 PM PST and filed on 1/30/2015

Case Name: Phillips v. C.R. Bard, Inc. et al

Case Number: 3:12-cv-00344-RCJ-WGC

Filer:

Document Number: 294(No document attached)

Docket Text:

MINUTES OF PROCEEDINGS - Jury Trial (DAY 5) held on 1/30/2015 before Judge Robert C. Jones. Crtrm Administrator: *Lesa Ettinger*; Pla Counsel: *Ramon Lopez, Troy Brenes, Julia Reed Zaic, Peter Wetherall*; Def Counsel: *Richard North, James Condo*; Court Reporter/FTR #: *Margaret Griener*; Time of Hearing: *9:06 a.m. - 10:06 a.m., 10:24 a.m. - 12:06 p.m., 1:39 p.m. - 2:59 p.m., 3:12 p.m. - 3:46 p.m.*; Courtroom: *6*; Also present in the courtroom: Kevin Phillips, Plaintiff; Candace Camarata on behalf of Defendants.

(9:06 a.m. - 12:06 p.m.) JOHN HANSEN, M.D. is called to the stand on behalf of the Plaintiff. The witness is sworn and testifies on direct and redirect examination by Mr. Ramon Lopez; cross and re-cross examination by Mr. Richard North, then excused. Plaintiff's exhibits 1030, 905, and 1071 are admitted into evidence. Defendants' exhibits 2660, 2661, 2662 and 2219 are admitted into evidence.

(1:39 p.m. - 2:59 p.m.) MICHAEL FREEMAN, MedDr., Ph.D., M.P.H. is called to the stand on behalf of the Plaintiff. The witness is sworn and testifies on direct and redirect examination by Mr. Troy Brenes; cross by Mr. Richard North, then excused. Plaintiff's exhibit 858 is admitted into evidence Defendants' exhibit 2816 is admitted into evidence.

(3:12 p.m. - 3:46 p.m.) KEVIN PHILLIPS is called to the stand. The witness is sworn and testifies on direct examination by Mr. Ramon Lopez.

Jury is admonished and excused. Court and counsel confer on evidentiary issues.

IT IS ORDERED that trial is continued to MONDAY, 2/2/2015 at 9:00 a.m. in Reno Courtroom 6 before Judge Robert C. Jones.

(no image attached) (Copies have been distributed pursuant to the NEF - LE)

3:12-cv-00344-RCJ-WGC Notice has been electronically mailed to:

James F. Rogers jim.rogers@nelsonmullins.com

Kelly A. Evans kevans@swlaw.com, DOCKET_LAS@swlaw.com, jmelnar@swlaw.com, jparsons@swlaw.com

Peter C Wetherall pwetherall@wetherallgroup.com, jgreening@wetherallgroup.com, ksmith@wetherallgroup.com

Ramon R Lopez rlopez@lopezmchugh.com

Jay Joseph Schuttert jschuttert@swlaw.com, DOCKET_LAS@swlaw.com, jparsons@swlaw.com, tstephenson@swlaw.com

Justin S Hepworth jhepworth@swlaw.com, docket_las@swlaw.com, jparsons@swlaw.com, mdaniel@swlaw.com

Richard B. North, Jr richard.north@nelsonmullins.com, mandy.evangelista@nelsonmullins.com, maria.turner@nelsonmullins.com

Taylor Tapley Daly taylor.daly@nelsonmullins.com, elie.wolfe@nelsonmullins.com

Matthew B. Lerner matthew.lerner@nelsonmullins.com

Troy A Brenes tbrenes@lopezmchugh.com, bmeyers@lopezmchugh.com, mwass@lopezmchugh.com

Lindsay K Eaton leaton@whiteandwetherall.com

Julia N Reed Zaic julia@HRZLaw.com

Elizabeth C. Helm kate.helm@nelsonmullins.com

James R. Condo JCondo@swlaw.com

Matthew E. Brown matt.brown@nelsonmullins.com

Jane T. Davis debbie.tolle@nelsonmullins.com

3:12-cv-00344-RCJ-WGC Notice has been delivered by other means to: